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TOP1

Outcomes After Surgical Intervention for Outflow Graft Obstruction in Magnetically-Levitated Centrifugal-Flow Left Ventricular Assist Device Patients

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Background: Outflow graft obstruction (OGO) is an under-reported but potentially devastating complication after insertion of magnetically levitated centrifugal flow left ventricular assist devices (LVAD). The optimal treatment and long-term outcomes have not been well-described to date. We report a single high-volume center's experience with these cases and their long-term outcomes.

Methods: We retrospectively reviewed all LVAD insertions at our institution from June 2019-October 2023 and identified cases of OGO.

Results: OGO was identified among 18 LVAD recipients among 550 LVAD recipients (3.3%). Median presenting age was 66 years and median time of LVAD support was 32.5 months. Low-flow alarms with/without symptoms (66.6%) was the most common presentation, followed by dyspnea on exertion (55.5%), and syncope (16.6%). Computed-tomography angiography (CTA) was the most common diagnostic modality (83.3%), though graft angiography and right-heart catheterization were used in inconclusive cases (16.6%). Aortic valve opening with every beat was present on echocardiography for 72% of patients with OGO. Among these, 38% were previously immobile on the most recent prior echocardiogram, 15% intermittently opened, and 30% opened with every beat. Half of all cases showed an increase in mitral valve regurgitation by at least one grade. All cases were treated with surgical re-exploration to alleviate the obstruction. In 78% of cases, a left anterior thoracotomy was performed while 22% underwent a re-do sternotomy. Intraoperative findings included outflow graft twisting alone (11%), twisting and extrinsic compression (37.5%), and extrinsic compression alone (56%). In all cases of extrinsic compression, a proteinaceous material was identified between the bend relief and the outflow graft. Excision of the bend relief and evacuation of this material immediately improved hemodynamics, LV unloading, and LVAD function. There were no in-hospital mortalities, and all patients were discharged home after a median length of stay of 19 days. All but 3 patients were alive at follow-up (median follow-up 21 months) - one patient died of a cardiac arrest, one from intentional transection of the LVAD driveline, and unknown etiology for the third. One patient required an LVAD exchange for recurrent outflow obstruction. Twelve of the eighteen patients were readmitted a total of 56 times but only one of the readmissions was for recurrent VAD obstruction. Our center currently advocates creating perforations in the outflow graft bend relief to help prevent this condition.

Conclusions: Surgical exploration via a left thoracotomy rectifies LVAD OGO with durable outcomes. Persistent aortic valve opening on echocardiography and CTA imaging are useful in confirming the diagnosis. Recurrent heart failure symptoms or low-flow alarms warrant evaluation for this condition.

TOP2

Platelet Aggregation is Influenced by Nitric Oxide Loaded Liposome Nanoparticle Formulation

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Background: Thrombosis management, usually with heparin or anti-platelets, is often associated with serious bleeding and thrombocytopenia, particularly with renal or hepatic failure, due to irreversible binding, long half-life of antagonist binding and systemic action. We aimed to address these gaps in thrombosis management with the development of a lipid-based nanoparticle for targeted delivery of nitric oxide (NO) to platelets.

Methods: The estimated half-life of NO in blood is 0.05-1.8 milliseconds (1) and its off-target effects could be addressed with the incorporation of targeting ligands and or platelet membranes into the liposome NO carrier shell. Liposomes were formulated using the thin-film hydration method (2). Briefly, a lipid film composed of 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), fluorescent lipids, PEG-maleimide, with ad without fibrinogen (fg) was prepared. DMHD/N₂O₂ (3), a model NO donor, was encapsulated into liposomes and extruded. Unincorporated materials were removed by gel permeation chromatography using Sephadex G-25 resin after extrusion. Liposomes were characterized for NO release and size distribution using a NOA 280i, TEM, and DLS, and for toxicity and platelet aggregation using human fibroblast and human platelet-rich plasma incubation.

Results: Average liposome size, zeta potential, and polydispersity index were 70 nm, -29.5 mV, and 0.47, respectively (Figure 1). NO flux from 100 μ L (~120, 70 nm liposome spheres) samples at pH 5.5 and pH 7.34 were 598.4 ($\times 10^{-5}$ moles/min/cm²) and 79.8 ($\times 10^{-5}$ moles/min/cm²) respectively. TEM and UV-vis spectra showed liposome formation and light interaction differences among liposome formulations. Platelet aggregation with ADP, empty liposome, fg-grafted liposome, or NO loaded fg-grafted liposome incubation with platelet rich plasma (4:1, v/v) showed aggregation inhibition effects of the latter formulation (Figure 2). NO loaded liposome solution mixed into cell growth media at 1:2 and 1:1 (v/v) mixtures exhibited toxicity to cells after 72 hrs of incubation. No toxicity was observed at 1:4 mixtures.

Conclusion: Liposome formulation with NO inhibits platelet aggregation, highlighting its potential therapeutic relevance in thrombosis management. These findings warrant further comprehensive studies to elucidate underlying mechanisms and optimize delivery methods.

Reference

(1) J Biol Chem 2000. 275:2342-2348. (2) Macromolecular Bioscience 23.4 (2023): 2200479. (3) Eng Press. 2018; 2(1): 66-72. <http://publishingpress.info/engineering-press/>

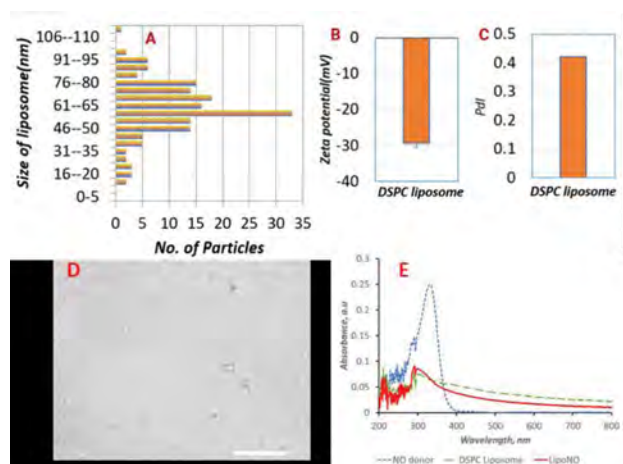


Figure 1. Size distribution, zeta potential, and Pdi (A-C), TEM of liposomes (D) and wide scan UV-vis spectra of free NO donor (dashed curve), DSPC only liposome (long dashed curve), and liposome with NO (solid curve). Abbreviations: UV vis, ultraviolet visible; DSPC, distearoylphosphatidylcholine.

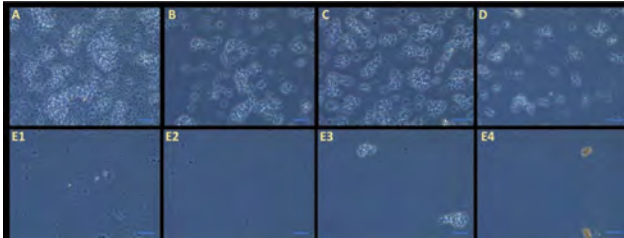


Figure 2. Fluorescent microscopy of platelet aggregation of 1 hour incubated (37°C, agitation at 37 RPM) human platelet rich plasma in 96 well plate without agonist (A), and with ADP agonist interaction (B), empty liposome construct interaction (C), fibrinogen-grafted empty liposome construct interaction (D), and nitric oxide encapsulated fibrinogen-grated liposome construct interaction (E1-4) Scale bar (100 µm).

TOP3

Regional Variation in Ventricular Assist Device Utilization and Waitlist Outcomes for Children Listed for Heart Transplantation in the United States Before and After the 2016 Pediatric Allocation Policy Change

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Background: The 2016 United Network for Organ Sharing (UNOS) allocation change was implemented to improve waitlist (WL) survival for children listed for heart transplantation (HT). Ventricular assist devices (VAD) have increased survival to HT for children with end-stage heart failure. The primary aim of this study was to evaluate regional variation in VAD utilization across the United States before and after the pediatric allocation policy change. The secondary aim was to evaluate regional variations in WL survival before and after the policy change.

Methods: Children (age <18 years, n=5736) listed for HT in the United States between 12/16/2011 and 12/31/2020 were identified from the Scientific Registry of Transplant Recipients database. Pre-policy change era was defined as the time from 12/16/2011 – 3/21/2016; post-policy change era defined as the time from 3/22/2016 – 12/31/2020. Differences in VAD utilization between the eras and within each region were evaluated pre- and post-policy change. WL survival was assessed using competing risk methodology. Subsequently, a multi-phase parametric hazard model was utilized to assess differences in WL survival between the pre-and post-policy change eras.

Results: VAD utilization increased nationally post-policy change (10 vs. 15%, p<0.001). Evaluating VAD utilization by UNOS regions, 5 regions demonstrated a significant rise in VAD utilization post-policy change (3, 4, 7, 9, 10) (Table). WL survival did not improve nationally post-policy change (p=0.17). When evaluating WL survival by region post-policy change, regions 6, 8 and 9 demonstrated increased mortality, while regions 1, 2, 4, 7, 9, 10 and 11 demonstrated improved WL survival (Figure).

Conclusions: The most recent pediatric policy change has led to significant variation in VAD utilization and WL survival across the United States. Nationally most regions with higher VAD utilization had improvement in WL survival. Identifying and addressing factors associated with geographic variations in VAD utilization may help improve WL survival for children requiring HT.

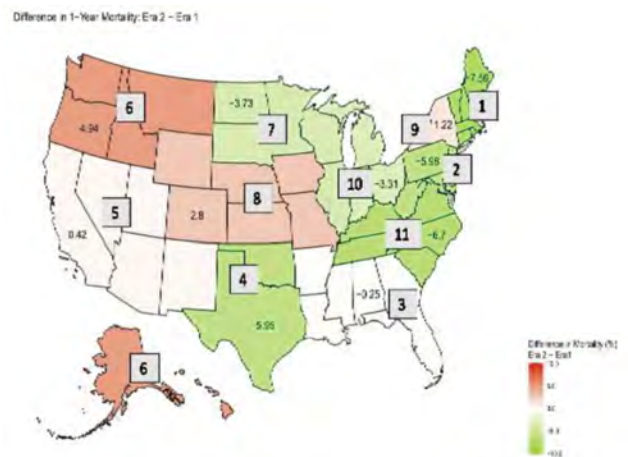


Figure 1. Difference in 1-year waitlist mortality between Era 1 and Era 2, stratified by UNOS region. Green regions show a decrease in mortality from Era 1 to Era 2. Red regions indicate an increase in mortality from Era 1 to Era 2.

Table 1. VAD Usage Stratified by Region and Era

UNOS Region	Era 1		Era 2		P-value
	Total Waitlist Candidates (N)	VAD N(%)	Total Waitlist Candidates (N)	VAD N(%)	
Region 1	88	13 (14%)	76	13 (17%)	0.68
Region 2	216	41 (18%)	224	52 (23%)	0.27
Region 3	442	26 (5.8%)	465	49 (10.5%)	0.011
Region 4	235	23 (9.8%)	297	56 (19%)	0.0039
Region 5	397	47 (12%)	486	77 (16%)	0.089
Region 6	81	5 (6.2%)	107	8 (7.5%)	0.73
Region 7	238	20 (8.4%)	326	60 (18%)	0.0008
Region 8	240	26 (11%)	307	49 (16%)	0.084
Region 9	146	17 (12%)	184	41 (23%)	0.012
Region 10	208	18 (8.7%)	277	46 (17%)	0.01
Region 11	273	23 (8.4%)	421	39 (9.3%)	0.71
All Regions	2564	259 (10%)	3172	490 (15%)	<0.0001

TOP4

Extended Duration of Impella 5.5 Support Does Not Adversely Impact Outcomes Following Heart Transplantation: A UNOS Registry Analysis

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Background: Impella 5.5 is increasingly employed as a bridge to transplantation. Prior studies assessing the effects of Impella 5.5 support duration on post-transplant outcomes have been limited to single-center case reports and series. Utilizing a national registry database, this study aims to comprehensively evaluate the impact of Impella 5.5 support duration on outcomes following isolated, primary heart transplantation.

Methods: The UNOS registry was queried to analyze adult heart transplant recipients who were bridged to transplantation with Impella 5.5 from 12/1/2019 to 3/31/2023. Recipients with concomitant or sequential support with veno-arterial extracorporeal membrane oxygenation or intra-aortic balloon pump were excluded from the study. Impella support duration was defined as the time interval between device implantation and transplantation dates. The cohort was stratified into 2 groups, ≤14 days and >14 days of Impella 5.5 support. Baseline recipient, donor, and transplant characteristics were compared between the groups. Primary outcomes included post-transplant 90-day survival and complication rates. Sub-group analysis was performed to evaluate the impact of >30 days of Impella 5.5 support on survival.

Results: A total of 307 recipients were analyzed. Of these, 200 recipients (65.1%) had Impella support duration >14 days with a median support duration of 27 days. The annual numbers of standard and extended duration of Impella 5.5 support have increased during the study period (Figure A). The recipients with >14 days of support had lower pre-transplant serum total bilirubin (0.97 vs 1.19 mg/dL, p=0.014), a reduced rate of pre-transplant inotropic support (56.0% vs 68.2%, p=0.037), younger donor age (31 vs 34 years old, p=0.022), and longer waitlist time (18.5 vs 6 days, p<0.001). The recipients with >14 days of support had similar 30-day (98.4% vs 100%) and 90-day (97.7% vs 97.5%) post-transplant survival compared to the recipients with ≤14 days of support (p=0.940, Figure B). Furthermore, the rates of post-transplant dialysis, stroke, permanent pacemaker insertion, acute rejection requiring medical therapy, and hospital length of stay were comparable between the groups (Table). In the sub-group analysis, the recipients with ≥30 days of support had equivalent 30-day (98.8% vs 98.1% vs 100%) and 90-day (98.8% vs 97.0% vs 97.5%) post-transplant survival compared to the recipients with 15-30 days and ≤14 days of support, respectively (p=0.799, Figure C).

Conclusion: The incidence of extended duration of Impella 5.5 support continues to increase. Extended use of Impella 5.5 does not adversely impact early post-transplant outcomes. This study highlights the safety and efficacy of Impella 5.5 as a bridge to transplantation.

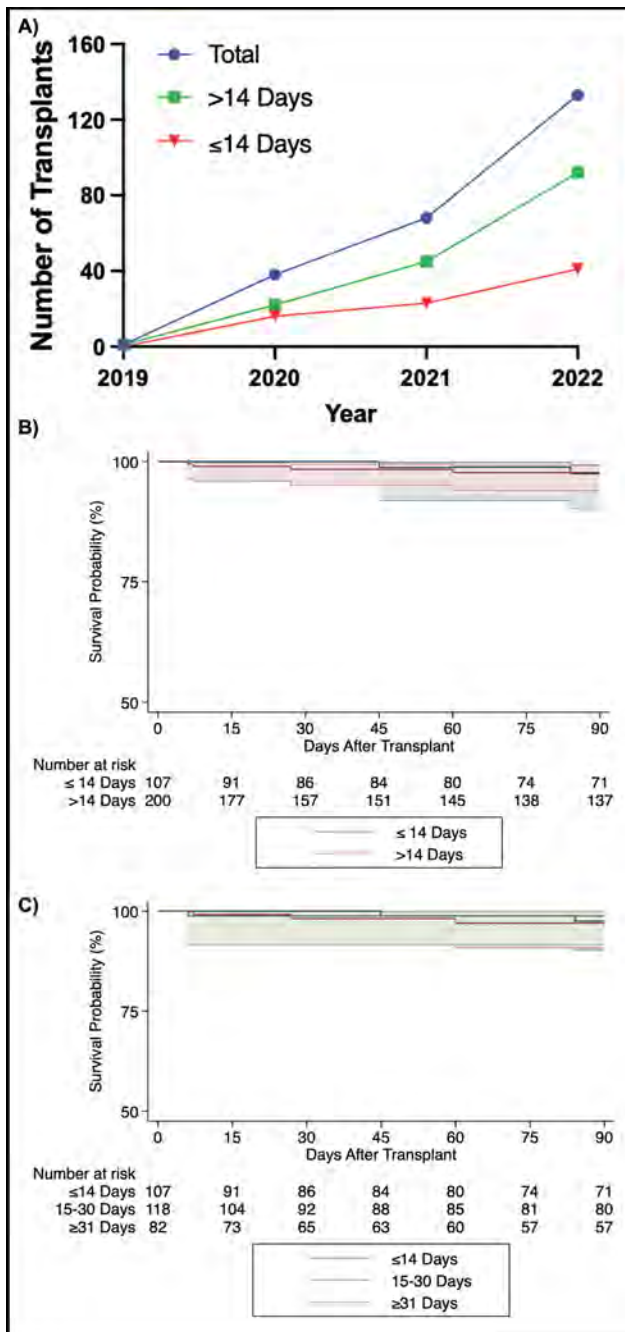


Figure 1. A) Annual number of patients bridge to transplant with Impella 5.5 stratified by support duration. **B-C)** Kaplan-Meier estimates with 95% confidence intervals for 90-day survival following heart transplantation stratified by Impella 5.5 support duration.

Table 1. Post-transplant outcomes stratified by Impella 5.5 support duration.

	≤14 days (n=107)	>14 days (n=200)	P-value
Dialysis	8 (7.5%)	15 (7.5%)	0.99
Stroke	3 (2.8%)	4 (2.0%)	0.65
Permanent pacemaker	1 (0.9%)	2 (1.0%)	0.95
Hospital length of stay (days)	15 [11-20]	16 [12-22]	0.24
Treated acute rejection	10 (9.3%)	23 (11.5%)	0.56

TOP5

Population-Level Impact of Ex-Vivo Lung Perfusion in Lung Transplantation

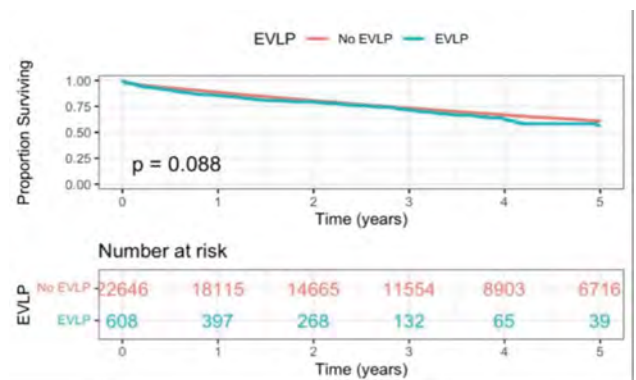
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Background: Ex-vivo Lung Perfusion (EVLP) is a novel organ preservation technique introduced to assess extended lung donors and determine their suitability for human use. The implementation of EVLP has allowed transplant programs to increase lung transplantation numbers without significantly impacting outcomes. Data on the use of EVLP at the population level is lacking, particularly access to this technology and recipient outcome variations.

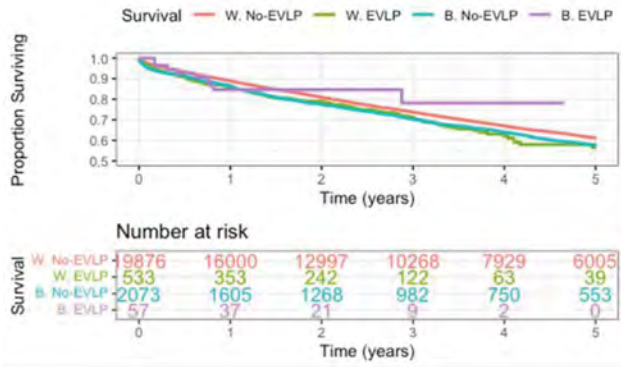
Methods: This retrospective cohort study analyzed lung transplant recipients in the U.S. from 2011-2021, with data from the Scientific Registry of Transplant Recipients (SRTR) via the United Network for Organ Sharing (UNOS). An Institutional Review Board was obtained before requesting data. Kaplan Meier Curves were used for time-to-event survival analysis, and the cox-proportional hazards model was used for determining hazard ratios for 5-year survival.

Results: Of 23,261 patients, 608 had EVLP-donor lungs. Five-year survival was similar across groups (Graph 1). Centers with EVLP access had median wait times of 48 days (SD 260.80) versus 68 days (SD 273.73) at other centers. Cox Proportional Hazards model showed no significant disparity in five-year survival with EVLP (HR 1.17, p=0.061). Factors like double lung transplant (HR 0.73, p<0.01), perioperative ECMO (HR 1.33, p<0.01), center volume (HR 0.82), and recipient race (HR 1.18, p<0.01) influenced survival. Survival differed across race and EVLP status groups. Excluding Black EVLP, white non-EVLP had significantly higher survival (Graph 2). Black EVLP recipients showed a nonsignificant trend toward survival benefits in comparison with Black non-EVLP recipients (Graph 3)

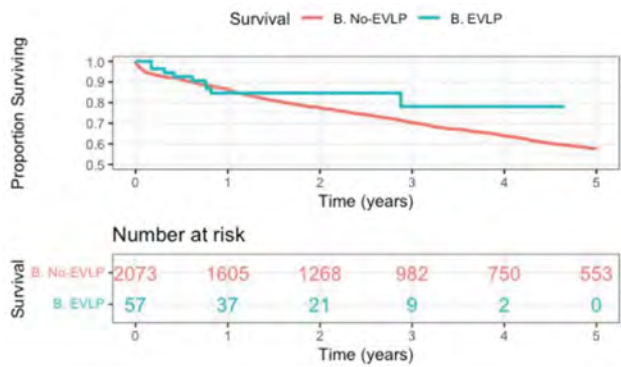
Conclusions: EVLP has not adversely affected five-year survival rates in lung transplantation recipients and is associated with shorter wait times. Survival is influenced by transplant type, ECMO use, center volume, and race. A survival advantage in black recipients with EVLP-assessed lungs suggests a need for further study. Exploring population-level differences in organ preservation devices is needed to assess disparities involving access or implementation of novel technologies.



Graph 1. Kaplan-Meier 5-Year Survival Curve Stratified by EVLP Assessment in SRTR Database from 2011-2021



Graph 2. Kaplan-Meier 5-Year Survival Curve for White and Black Lung Transplant Recipients with and without EVLP: SRTR Database 2011-2021.



Graph 3. Kaplan-Meier 5-Year Survival Curve Comparison of Black Lung Transplant Recipients with and without EVLP in the SRTR Database (2011-2021).

TOP6

Removal Of Large-Middle Molecules, Inhibition Of Neutrophil Activation And Modulation Of Inflammation-Related Endothelial Dysfunction In Chronic Uremic Patients Treated By Expanded Hemodialysis (Hdx)

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Background: HemoDialysis expanded (HDx) represents an innovative strategy to remove uremic toxins of Large-Medium Molecular weight (LMMs, ≤ 45 Kda) thanks to membrane medium cut-off (MCO). Some LMMs (in particular Free Light Chains-FLC) inhibit neutrophil apoptosis leading to persistent inflammation, endothelial dysfunction and increased cardiovascular risk in chronic uremic patients.

Aims of the study were to evaluate: 1) efficacy of HDx on LMM removal and decrease of inflammatory parameters; 2) *in vitro* effects of plasma drawn from patients (T0 and T6 months) on neutrophil activation and endothelial dysfunction.

Methods: 60 HD patients (age 67.6 ± 13.4) in standard high flux HD were shift to HDx using TheraNova® 400 (1.7 m², Baxter). Each patient was studied at baseline (T0), 3 months (T3) and 6 months (T6) after HDx start. We evaluated the following pre-dialysis parameters: Urea, Creatinine (Creat), Phosphate (P), Beta2-microglobulin (B2m), Myoglobin (Myo), Free Light Chains (FLC-k, FLC- λ), Hemoglobin (Hb), Albumin and C Reactive Protein (CRP). For *in vitro* studies, T0 and T6 plasma were used to evaluate neutrophil activation (ROS generation, apoptosis, adhesion) and endothelial dysfunction/senescence.

Results: HDx therapy was well tolerated without evidence of major adverse side effects. After 3 months of HDx (T3), we observed a significant decrease of urea ($p=0.008$), B2m ($p=0.003$), FLC-k ($p=0.026$) and FLC- λ ($p=0.001$). No significant differences of the other uremic toxins between the periods (T3 vs. T6) were observed. Albumin levels remained stable during all the study period. A significant decrease of CRP was observed at T3 and T6, suggesting a positive effect of HDx on inflammatory parameters correlated with a worse outcome. *In vitro* studies confirmed that LMM removal by HDx associated with a limitation of neutrophil activation (significant decrease of ROS, TNF-alpha and IL6 production, increase of apoptosis assessed by TUNEL and caspase-3 ELISA) and of endothelial dysfunction (significant decrease of neutrophil adhesion, increased NO bioavailability and angiogenesis, inhibition of vascular senescence with increased expression of the anti-oxidant factor Nrf2). Preliminary data revealed a potential role of HDx in the modulation of the microRNA content of circulating extracellular vesicles (EV) isolated from patients' plasma.

Conclusions: HDx therapy removes different LMMs including FLCs leading to a decrease of uremia-associated inflammation and vascular dysfunction. Our preliminary clinical data and *in vitro* studies suggested that by improving LMM removal, HDx may limit neutrophil activation and endothelial dysfunction, key factors of the increased cardiovascular risk of hemodialysis patients. A modulation of EV-carried microRNA involved in vascular aging can also be hypothesized. However, long-term studies with a larger sample size are needed to evaluate the clinical impact of HDx.

TOP7

Neonatal Outcomes Following Maternal Antepartum Extracorporeal Life Support

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Background: Fetal distress can occur any time that maternal physiology is deranged. The basic tenant of fetal support is initiation of interventions that optimize maternal physiology to restore uterine blood flow and oxygen delivery to the fetus. In cases of medically refractory respiratory failure or cardiogenic shock, extracorporeal life support (ECLS) may be required. There are multiple examples of improved maternal and fetal survival when ECLS is instituted in a timely fashion. The paucity of data regarding neonatal postpartum outcomes and subsequent neurodevelopment after exposure to antepartum ECLS warrants further investigation.

Methods: Single-center retrospective review of all children that were in-utero when maternal ECLS was provided. Short-term outcomes of interest include additional gestation gained while on ECLS, neonatal survival to hospital discharge, length of stay, and additional comorbidities diagnosed in-hospital. Long-term outcomes of interest included the development of additional comorbidities and neurodevelopmental progression.

Results: All neonates survived to delivery (N=7) and subsequently to discharge with an average increased gestation of 4 weeks from ECLS initiation to delivery. Six (86%) were delivered while on maternal ECLS. Neonatal length of stay was 50.7 ± 10.1 days, and all were discharged home. The most common comorbidity diagnosed was bronchopulmonary dysplasia in 3 (43%). There were no hemorrhagic complications. One (14%) neonate required percutaneous closure of a patent ductus arteriosus (PDA). Outpatient follow-up demonstrated no early hospital readmissions and minimal additional comorbidities, most commonly otitis media. Neurodevelopmental assessment was available on 4 patients at a follow-up duration of 17 ± 5.8 months which demonstrated delays in 2 (50%) patients, both related to speech and language.

Conclusion: The first investigation into neonatal outcomes after antepartum ECLS demonstrates that it can be utilized safely with no apparent complications in this cohort. Utilization of ECLS allowed fetuses to reach increased gestational age at delivery which is associated with improved survival and subsequent milestone progression in non-ECLS exposed neonates. Future investigation should focus on long-term formal assessment to better characterize the incidences of neurodevelopmental delay seen in this cohort.

Neonatal Outcomes Following Maternal Antepartum Extracorporeal Life Support

	N=7
Gestational age at time of initial admission	26.1 $\pm$ 1.5
Gestational age at time of ECLS initiation (weeks)	26.6 $\pm$ 1.5
Gestational age at time delivery (weeks)	30.3 $\pm$ 1.2
Delivered while on maternal ECLS	6 (86%)
APGAR at 1 minute	3.6 $\pm$ 1.0
APGAR at 5 minutes	5.4 $\pm$ 0.8
APGAR at 10 minutes	5.8 $\pm$ 0.7
Neonatal survival to discharge	7 (100%)
Length of stay (days)	50.7 $\pm$ 10.1
Duration of invasive mechanical ventilation (N=5) (days)	6.2 $\pm$ 5.2
Surgical intervention required before discharge	1 (14%)
Bleeding complications	0 (0%)
90-day hospital readmission	0 (0%)
Neurodevelopmental delay identified (N=4)	2 (50%)
Average length of neurodevelopmental follow-up (months)	17 $\pm$ 5.8

Data displayed as N (%) and mean $\pm$ standard error of the mean for categorical and continuous variables respectively.

CARC1

Neuroimaging Evidence of Preexistent Regional and Global Brain Atrophy Association With LVAD-Related Neurological Dysfunction

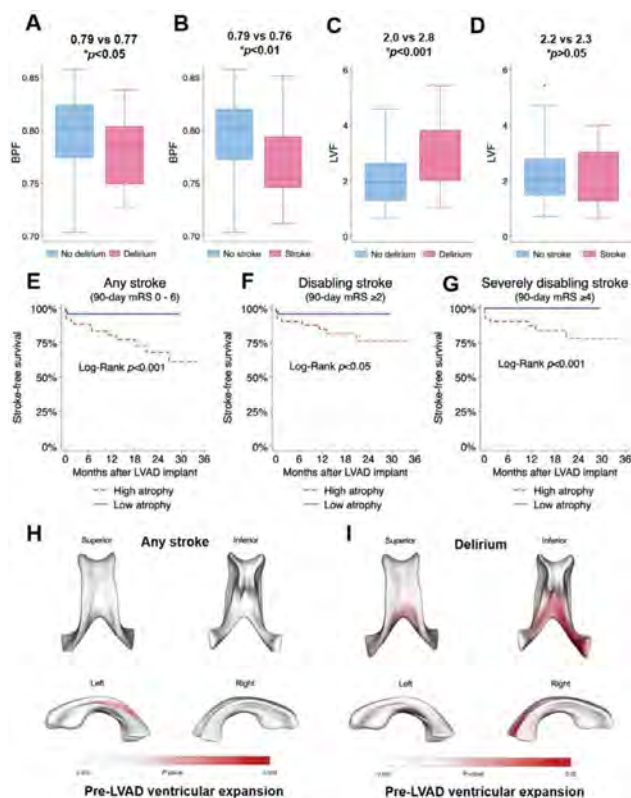
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Background: Determine the degree and pattern of brain structural changes of patients developing neurological dysfunction (ND), as defined by INTERMACS (any neurological event with or without imaging evidence of structural damage) related to left ventricular assist device (LVAD).

Methods: This is a prospective study with a total of 105 patients with advanced heart failure (ADHF) undergoing LVAD insertion from March 2021 to July 2023. All patients underwent a non-contrast clinical CT scan of the brain before LVAD implantation. Scans were pre-processed and post-processed with a deep learning-based pipeline. Regional and brain atrophy were assessed with lateral ventricle fraction (LVF) and brain parenchymal fraction (BPF), respectively. Regression models and mean differences comparisons were adjusted to age and LVAD device. Multiple comparison correction was conducted with a false discovery rate (FDR) with a p-value threshold of 0.05.

Results: The mean difference of baseline BPF was significantly lower in patients experiencing post-LVAD delirium (Fig.A) and post-LVAD stroke (Fig.B). In addition, the mean difference of baseline LVF was significantly higher in patients experiencing postoperative delirium (Fig.C), and baseline LVF was not significantly different in patients sustaining any type of post-LVAD stroke (Fig.D). Kaplan-Meier survival curves indicated that, when classifying patients into low baseline (BPF $\geq$ 0.80) or high baseline (BPF<0.80) brain atrophy, patients with higher baseline brain atrophy had a significantly increased risk of experiencing any stroke (Fig.E), any disabling stroke (Fig.F), and severely disabling stroke (Fig.G). Average mesh representation displayed pre-LVAD lateral ventricles shape differences (after FDR-correction) of patients sustaining stroke or delirium after LVAD implant, in comparison with patients who did not sustain any ND. Patients who experienced any type of stroke (Fig.H) or delirium (Fig.I) had a significantly different shape of regional brain atrophy, as demonstrated by shape expansion on cerebral lateral ventricles. Patients developing post-LVAD stroke displayed higher baseline ventricular expansion over the left lateral body, whilst post-LVAD delirium patients demonstrated higher baseline ventricular expansion over the medial right and left aspects of the posterior horns (Fig.H,I).

Conclusions: Preexistent regional and global brain atrophy is an important ND risk factor, and their quantification can be incorporated into the workup of LVAD. Our work provides promising findings about the use of neuroimaging biomarkers that could be employed for the prevention of ND in patients with high risk and improve the selection of patients.



CARC2

Characterization of Late-onset Right Ventricular Failure in Patients with Left Ventricular Assist Device

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Background: Late-onset right ventricular failure (RVF) is a common cause of significant morbidity and mortality in patients undergoing left ventricular assist device (LVAD) implantation. However, it remains incompletely understood, given that current research primarily focuses on identifying and managing early RVF post-implantation and the inconsistent definitions of this complication across studies. This study investigates the incidence and clinical features associated with late-onset RVF in LVAD patients.

Methods: This retrospective cohort study included individuals who underwent LVAD implantation at the University of Washington, with at least 30 days of support. The Mechanical Circulatory Support Academic Research Consortium criteria was used to adjudicate late-onset RVF arising more than 30 days post-implantation. The outcomes of interest included time to late-onset RVF and mortality on LVAD support. Potential causal factors were examined using cause-specific models accounting for the competing events, transplant, or cardiac recovery prompting LVAD explantation. Mortality risk associated with late-onset RVF as a time-varying exposure after LVAD implantation was evaluated using Cox regression models.

Results: The cohort consisted of 497 LVAD recipients from 2005–2021, with a median age of 57 years, 18% women, and 75% Caucasian. Late-onset RVF criteria was met by 120 subjects, with the estimated cumulative incidence of late-onset RVF being 24.1 cases per 100 individuals at risk. Cause-specific competing risk analysis revealed associations between higher body mass index (HR 1.05, 95% CI 1.01–1.08; $p=0.01$), longer cardiopulmonary bypass time (HR 1.04, 95% CI 1.02–1.07; $p<0.001$), centrifugal pump (HR 2.05, 95% CI 1.29–3.28; $p=0.003$), and pulmonary artery pulsatility index (PAPi) less than 2 (HR 2.20, 95% CI 1.24–3.89; $p=0.007$), with late-onset RVF development. Conversely, the use of temporary mechanical circulatory support (MCS) pre-LVAD implantation was linked to a lower risk of late-onset RVF (HR 0.46, 95% CI 0.29–0.74; $p=0.001$). After adjustment, late-onset RVF was significantly related with an increased mortality risk (HR: 2.8, 95% CI: 2.0–4.0 $p<0.001$).

Conclusion: This study reveals late-onset RVF as a prevalent complication associated with elevated mortality in post-LVAD patients. PAPi<2 was the strongest predictor for late-onset RVF, while temporary MCS support before LVAD was noted to be a protective factor. Future investigations should look at a broader and more diversified population to further characterize the impact of this complication.

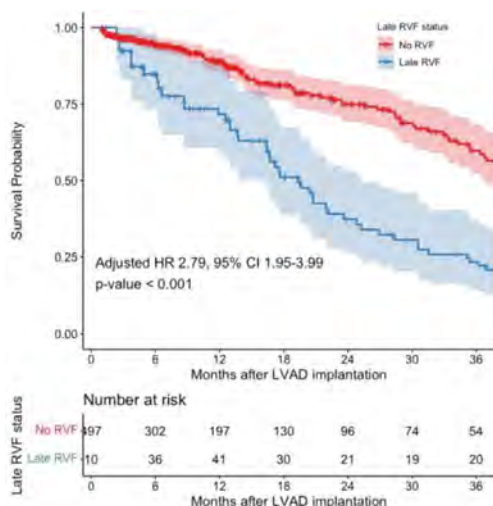


Figure 1. Kaplan-Meier curve depicting reduced survival probability in patients with late-onset RVF post-LVAD implantation.

CARC3

Enhancing Hospice Patient Comfort: A Novel 3D-Printed Solution for HeartMate 3 Alarms

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Purpose: Mitigating alarms in Hospice care LVAD patients to enhance the end-of-life experience for patients and their families.

Background: The HeartMate 3, a left ventricular assist device (LVAD), is a life-saving tool for patients with severe heart failure. Persistent Low Flow Alarms in LVAD patients in hospice arise from changes in patient physiology, triggering the device to detect reduced cardiac output and lower blood flow. In attempts to address this issue, caregivers or VAD coordinators can use scotch tape on the controller speaker holes to dampen the sound, which provides limited relief.

Methods: We designed a 3D printable design to fit the HeartMate 3 controller. The design aimed to dampen the sound of the alarms without compromising with their functionality. The prototype was printed using Thermoplastic Polyurethane (TPU), chosen for its flexibility and durability. In addition, the 3D.stl file was sliced with max infill to have the highest resolution and allow for accurate measurements. Sound Comparisons were done using a mobile app, Decibel X, which measures the sound decibels. To assess the 3D printed design's effectiveness, sound comparisons were made during hazardous alarms at 0ft and 3ft (A caregiver would stand 3 feet from the patient), comparing normal, scotch tape, and our 3D print (See Table 1) Baseline sound measurements were taken at the same distances without alarms.

Results: TPU filament resulted in a flexible prototype with easy usage (See Table 2). The product's minimalistic design did not interfere with controller functionality. The implementation of the 3D printed part resulted in a significant reduction in the sound level of the alarms, specifically, a decrease of approximately 30 dB between the alarming controller and the controller equipped with the sound dampener. The prototype also outperformed the scotch tape method.

Conclusion: Providers can 3D print the sound dampener and use it on a need basis. The reduction in Alarm sound is expected to improve the comfort and life quality of hospice patients and their families, using the HeartMate 3. The global accessibility of 3D printers provides easy and cost-effective access to healthcare providers.

Table 1. Alarms Sound measured in Decibels

Distance (ft)	Normal (no Alarms)	Alarm (no Dampener)	Alarm with Scotch Tape	Alarm with Sound Dampener
0	46.7dB 	95.6dB 	87.4dB 	65.4dB
3	40.0dB 	76.2dB 	69.3dB 	44.4dB

Table 1. Alarm Sound measured in Decibels

Table 2. Sound Dampener Prototype

CARC4
State of Durable Left Ventricular Assist Device Under New UNOS Heart Allocation Policy

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Background: It has been widely reported that durable continuous flow left ventricular assist device (CFVAD) use declined under the new united network for organ sharing (UNOS) heart allocation (in effect since October 2018). We aimed to evaluate CFVAD support under new policy and its post-transplant outcomes.

Methods: The UNOS thoracic transplant database was queried from January 2010 to June 2023 for adult (age>17years) patients listed for heart transplantation (HTx). The CFVAD patients included were Heartware HVAD, Heartmate 2 and Heartmate 3 devices. The data was initially divided in two groups based on implementation of the policy: Old and New. The data was also divided based on use of CFVAD v. Non-CFVAD. The non-CFVAD group included patients with no mechanical circulatory support and percutaneous temporary support devices. Total heart and biventricular support patients were excluded.

Results: There were 50,745 patients listed since 2010 of which 30,834 (61%) were under old policy and 19,911 (41%) were under new policy. The CFVAD use declined under the new policy (13,235/30,834 (42%) old v. 4887/19,911 (25%) new, $P<.01$). Of 13,325 old policy CFVADs, 6188 (46%) had implantation prior to HTx listing whereas of the 4887 new policy CFVADs 4017 (82%) had implantation prior to listing ($P<.01$). For the patients receiving CFVAD before HTx listing the median duration of support before listing was significantly higher under the new policy (209 (97-399) old v. 400 (213-808) new $P<.01$, Figure 1). CFVAD post HTx survival at 1-year was lower under new policy (87% v. 90% (old), $p<.01$, Figure 2A). Of 4887 new policy CFVADs 2913 (60%) were transplanted (7% status 1, 23% status 2, 39% status 3, 31% status 4). The 1-year post HTx survival under the new policy was not statistically different for statuses 1, 2, 3 and 4 (respectively 85%, 86%, 88%, 88%, $p=0.49$, Figure 2B).

Conclusion: Among the CFVAD patients listed under the new policy, most of them were implanted prior to their listing for transplant, indicating a conversion from an initial destination therapy approach to a bridge-to-transplant (BTT) approach. Because of the subsequent conversion to BTT in new policy era, these patients maybe at a higher risk compared to old policy era which is reflected by their inferior post HTx survival.

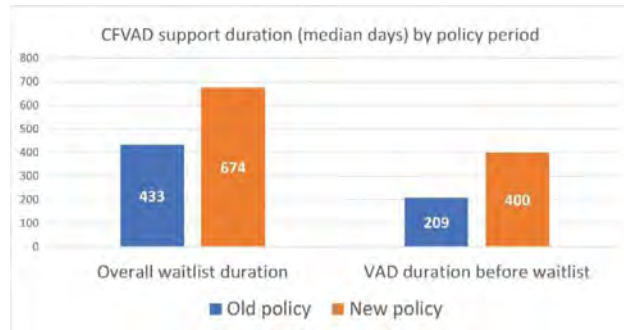


Figure 1. CFVAD patient median (Days) overall waitlist duration and VAD support duration before listing by policy period

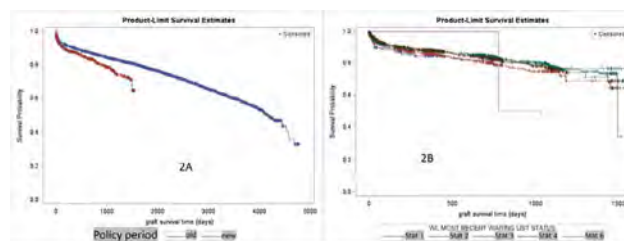


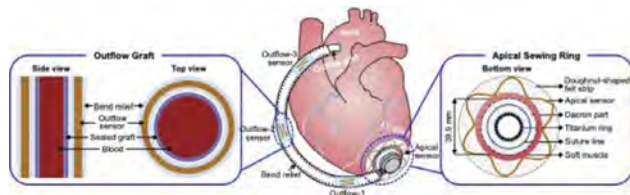
Figure 2. 2A) CFVAD post transplant survival by policy period; 2B) CFVAD Post transplant survival under new policy by urgency status at time of transplant

CARC5

Autonomous Control Algorithm To Meet Physiologic Demand For Left Ventricular Assist Devices Using Resonantly Coupled Sensors

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Rotary left ventricular assist devices (LVAD) currently operate at a fixed pump speed and are unable to meet physiologic demands. Additionally, they are susceptible to ventricular suction. To overcome these limitations, we developed a left ventricular end-diastolic volume (LVEDV) based physiologic control algorithm using resonantly coupled high-efficiency sensors (Fig 1,2). The resonantly coupled sensors consists of apical and outflow sensors and can accurately assess the ventricular chamber size with minimal long-term drift (~1%) at 9 months. The ability of the LVEDV based control algorithm was evaluated using an in-silico model of the human circulatory system coupled to an axial or centrifugal flow pump with 15% uniformly distributed volume measurement noise. The LVEDV setpoint was set to 85 ml, and the efficacy of the LVEDV control algorithm was evaluated and compared to constant pump speed control strategy during (1) rest and exercise states; (2) rapid, five-fold augmentation of pulmonary vascular resistance; and (3) rapid change in physiologic states between rest and exercise. Safety and robustness of the algorithm was also evaluated by incorporating a 6% volume drift (80 ml LVEDV setpoint). The LVEDV control algorithm provided sufficient physiological perfusion simultaneously and avoided ventricular suction (Fig 3) in all cases. Performance of the LVEDV algorithm was superior compared to maintaining constant pump speed for both types of LVAD, demonstrating pump independence of the proposed algorithm. There was no significant performance degradation of the controller with 15% volume measurement noise. The safety and efficacy of the LVEDV control algorithm coupled to a reliable sensor enables autonomous control of LVAD while avoiding suction.



Location of resonantly coupled sensors

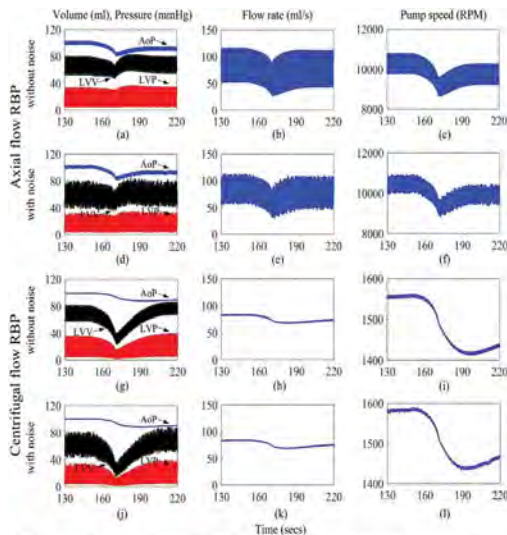


Fig. 2 In-silico results of the proposed pump-independent control algorithm at rest under the condition of 5-time pulmonary vascular resistance starting at $t = 150$ s for (a)-(c) the axial RBP without LVV measurement noise, (d)-(f) the axial RBP with LVV measurement noise, (g)-(i) the centrifugal RBP without LVV measurement noise, (j)-(l) the centrifugal RBP with LVV measurement noise.

Control algorithm avoided suction even with a 5 fold increase in pulmonary vascular resistance (at $t=150$ s).

CARC6

Trends and Predictors of Functional Class after Left Ventricular Assist Device Implantation at a Destination Therapy Center

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Introduction: Although left ventricular assist device (LVAD) implantation is associated with improved survival, the impact on functional class is less well understood. We undertook this study to better understand how LVAD implantation affects patient functional status.

Methods: We conducted a retrospective review of all primary LVAD implantations at a single center. Primary outcome was New York Heart Association (NYHA) functional class. An improved sustainable functional improvement was defined as being alive at 1-year with NYHA class I or II symptoms. Multivariable logistic regression was performed to identify predictors of sustainable functional improvement.

Results: From 2017-2023, 151 primary LVAD implantations were performed. Operative mortality was 7.95% ($n=12$). Prior to implantation, 119 (78.81%) patients were NYHA class IV and 32 (21.19%) were class III (IIIb). At 6-month follow-up, 113 (92.62%) of patients had experienced an improvement in functional class with 35 (28.69%) class I, 53 (43.44%) class II, 29 (23.77%) class III, and 5 (4.1%) class IV (Figure). At 12 months, 86 (91.49%) patients had sustained improvement in NYHA class with 32 (34.04%) class I, 40 (42.55%) class II, 19 (20.21%) class III, and 3 (3.19%) class IV. At 2 years, 57 (91.94%) patients still experienced improved symptoms. On multivariable logistic regression analysis, an ischemic etiology of heart failure was strongly associated with a sustainable functional improvement (OR: 5.53 [1.06-28.89], $p=0.04$; Table).

Conclusion: In conclusion, LVAD implantation is associated with significant functional improvement as measured by NYHA class. In our series, the best predictor of a sustainable improvement in functional status is an ischemic etiology of heart failure. Further investigation is warranted. Factors Associated with Improvement of Symptoms Following LVAD Implantation

Variable	Odds Ratio	95% Confidence Interval	p-value
Ischemic Etiology	5.53	[1.06-28.89]	0.04
Creatinine (mg/dL)	3.96	[0.75-20.82]	0.10
Preoperative Impella	0.35	[0.05-2.38]	0.28
Preoperative weight (kg)	0.98	[0.94-1.02]	0.31

CARC7

Patients who Utilize Interpreter Services Have an Increased Length of Stay and Increased INR Variability After LVAD Implantation

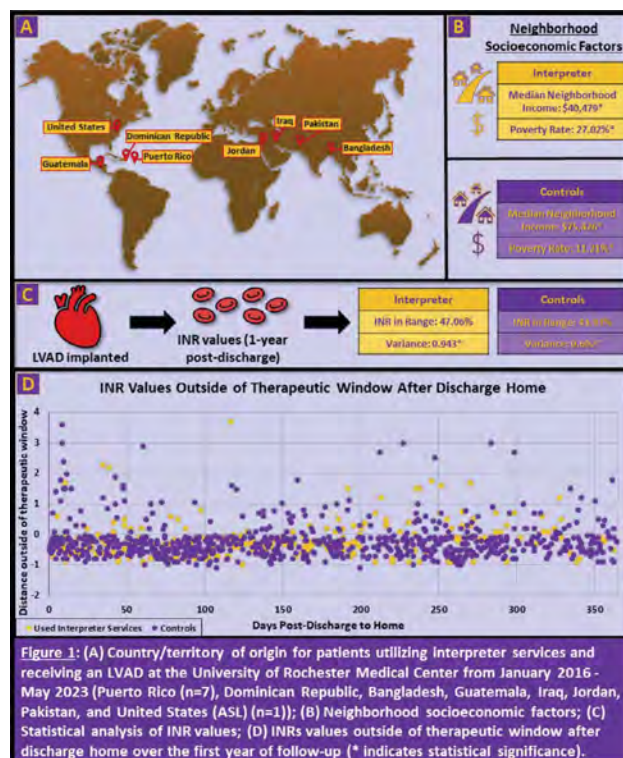
Benjamin Hauser¹, Andrew Jones¹, Sarah Hoffman¹, Ashwath Elangovan¹, Ariana Goodman², Madeline Fryer², Jenna Losapio³, Caroline Cuyler³, Jeffery Alexis⁴, Joy Choi⁵, Igor Gosev², Katherine Wood²; ¹*School of Medicine and Dentistry, University of Rochester, Rochester, New York, United States*, ²*Department of Surgery; Division of Cardiac Surgery, University of Rochester Medical Center, Rochester, New York, United States*, ³*Adult Social Work Services, University of Rochester, Rochester, New York, United States*, ⁴*Department of Medicine; Division of Cardiology, University of Rochester, Rochester, New York, United States*, ⁵*Department of Psychiatry, University of Rochester Medical Center, Rochester, New York, United States*

Background: Effective postoperative management of LVAD recipients requires frequent and clear patient-provider communication. Relationship building and information exchange is more complex with non-native English-speaking patients. The purpose of this study was to evaluate outcomes in LVAD patients who utilize interpreter services.

Methods: We retrospectively reviewed all patients (n=439) who underwent LVAD implantation between January 2016 and May 2023. A total of 15 patients had English documented as their second language with 14 (3.2%) using interpreter services. Baseline characteristics were evaluated, including education level, distance from hospital, employment status of patient/spouse, and insurance status. To assess socioeconomic factors of the neighborhood, census block group data were examined. Propensity score matching was performed based on the following variables: sex, surgical approach, age at implant, and concomitant procedures. One-year outcomes were evaluated, including INR variance, morbidity, and mortality, and analyzed with a multiple logistic regression to control for potential confounding.

Results: LVAD recipients utilizing interpreter services reside in census block groups with lower median household income levels (p<0.001) and higher poverty rates (p<0.001). Other baseline characteristics did not vary between groups. The length of hospital stay was prolonged for patients using interpreter services (35.5 vs. 20.9 days, p=0.044). The proportion of INR values in the therapeutic window over the first-year post-discharge did not vary between cohorts (47.1% vs 43.9%; p=0.229). However, patients who used an interpreter had a greater variance in INR values during the first year after discharge (0.943 vs. 0.602, p = 0.013), and greater variance in INR values outside the therapeutic window (0.552 vs. 0.248, p= 0.003). Other one-year outcomes including mortality, stroke, GI bleed, pump thrombosis, infection, and missed appointments did not vary between groups, even when controlling for local socioeconomic, and comorbid factors.

Conclusions: LVAD recipients who utilized interpreter services had increased hospital length of stay after index procedure and higher INR variance during the first post-operative year. These patients were also found to have lower socioeconomic status, which has been associated with lower health literacy. While this did not impact one-year mortality, increased INR variance places these patients at higher risk of perioperative complications. Additional research evaluating the impact of English as a second language, use of interpreter services, and lower socioeconomic status may help elucidate opportunities to optimize support systems, language barriers, and improve outcomes after LVAD implant.



CARC8

Transcatheter interventions in patients post durable left ventricular assist device

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Background: The widespread use of left ventricular assist devices (LVAD) has increased the life expectancy of the end-stage heart failure population. This growing population can develop subsequent valvular and ischemic disease post implant making them high risk for reoperations. We review the use of transcatheter interventions in this subgroup of high risk patients and its feasibility.

Methods: Retrospective and observational case series study of patients who underwent left ventricular assist devices and required further transcatheter interventions post implantation at a large academic institution from January 2016 to December 2023.

Results: Total of patients of 367 LVAD were implanted at our institutions within this time period. Of these patients, nine required transcatheter intervention. Five patients had a transcatheter transfemoral aortic valve replacement (TAVR) after developing severe aortic insufficiency post LVAD; Two of these had originally underwent concomitant aortic valve repair at the time of LVAD and developed worsening aortic insufficiency later on in their course; while 3 patients developed de novo AI. One patient had edge-to-edge mitral transcatheter repair after developing mitral regurgitation.

Two Patients underwent PCI post LVAD due to angina; One had stent in his proximal LAD and the other in the distal left main.

One patient had PCI Stents to the outflow graft of the LVAD.

Patient age range was 42 to 83 years old. Average time from implant to intervention was 42 months. All 9 patients are still alive and discharged after intervention.

Conclusion: Growing population of patients with LVAD implantation as destination therapy and good outcomes and survival, increase the number of other cardiac valvular or ischemic disease that require treatment later in their life. The transcatheter interventions are tools that can be used safely to prolong the quality of life in this high risk population, further studies should determine their specific applicability

CARC9

Bridging versus No Bridging in Left Ventricular Assist Device Patients undergoing Thoracentesis

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Background: Left ventricular assist devices (LVADs) pose thromboembolic risks requiring anticoagulation, with bleeding concerns. Current recommendations for anticoagulation involve using warfarin with a goal INR of 2-3 along with an anti-platelet agent. However, during periods of sub-therapeutic INR or during procedures, consensus on anticoagulation is lacking. A few strategies commonly used are bridging anticoagulation with heparin or enoxaparin, holding anticoagulation altogether, and continuing anticoagulation without interruption. Our study compares bleeding and thrombotic events in LVAD patients with or without bridging anticoagulation before elective thoracentesis, aiming to determine an optimal anticoagulation strategy during procedures, acknowledging the delicate balance needed to mitigate complications.

Methods: Data from patients with continuous flow LVADs undergoing thoracentesis at a large academic center was retrospectively collected over one year. The patient cohort was divided into a 'bridge' group (received intravenous heparin for bridging during the thoracentesis) and a 'no-bridge' group (did not receive bridging anticoagulation). Warfarin was paused pre-procedure and resumed post-procedure in both groups. Baseline characteristics, including age, sex, race, BMI, LVAD type, and INTERMACS profile, were recorded. Primary outcomes were major bleeding and thromboembolic events over a 30-day period from warfarin cessation. Statistical analysis utilized t-test/Wilcoxon for continuous variables and Chi-square/Fisher exact test for categorical variables. A p-value <0.05 was considered significant.

Results: During the study, twenty LVAD patients underwent thirty-two thoracenteses- nineteen in the bridge group and thirteen in the no-bridge group. Demographics are displayed in Table 1. Warfarin was held on an average of 5.5 ± 4.6 days before the procedure and resumed 4.1 ± 4.6 days after in the bridge group and in the no-bridge group it was held 3.8 ± 3.2 days before thoracentesis and resumed 1.7 ± 2.5 days after. Major bleeding occurred in 73.7% of cases in the bridge group versus 30.8% in the no-bridge group (p=0.059). 63.2% of patients in the bridging group had a bloody pleural effusion on thoracentesis compared to 46.2% in the no-bridge group (p value= 0.34). Average transfusion requirements were 2.8 units and 2 units in the bridge and the no-bridge groups respectively (p=0.658). Thromboembolic events included a 10.5% ischemic CVA rate in the bridge group, while none occurred in the no-bridge group. No other arterial thromboembolic events, pump thrombosis or DVT/PE were observed in either group.

Conclusion: In patients with LVADs undergoing elective thoracentesis, a strategy without bridging anticoagulation does not increase the risk of thrombosis or bleeding compared to bridging anticoagulation.

Table 1. Demographics

CHARACTERISTIC	BRIDGE GROUP (n=19)	NO-BRIDGE GROUP (n=13)
Age (years)	57.6 ±15.3	65.6 ± 12.0
Sex		
Males (%)	53.3	71.4
Females (%)	46.7	28.6
Race		
Caucasian (%)	26.7	28.6
African American (%)	73.3	71.4
Other (%)	0	0
BMI (kg/ m2)	24.6 ± 6.4	26.8 ±2.7
INTERMACS Grade		
Grade 1 (%)	13.3	14.3
Grade 2 (%)	33.3	28.6
Grade 3 (%)	33.3	57.1
Grade 4 (%)	20.0	0
LVAD Device type:	26.7	0
HeartMate3 (%)		
LVAD Device type:	73.3	100
HVAD (HeartWare) (%)		

Table 2. Bleeding and thromboembolic events among the two groups

	BRIDGE GROUP	NO-BRIDGE GROUP	p-value
Major Bleeding Events: number (%)	14 (73.7%)	4 (30.8%)	0.059
Source of bleed: number (%)			0.481
Gastrointestinal	7 (46.7%)	3 (60.0%)	
Central nervous system	2 (13.3%)	1 (20.0%)	
Thoracic/ Mediastinal	4 (26.7%)	0	
Genitourinary	1 (6.7%)	0	
Ear, nose, throat	0	1 (20.0%)	
Other	1 (6.7%)	0	
Pleural Effusion:: number (%)			0.341
Bloody	12 (63.2%)	6 (46.2%)	
Non-bloody	7 (36.8%)	7 (53.9%)	
Transfusion requirement: number of units	2.8 ± 2.5	2.0 ± 1.3	0.6581
Thromboembolic events: number (%)	2 (10.53%)	0	

CARC10

Impella 5.5 Outcomes in Patients Bridged to Heart Transplant

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Background: Following the 2018 United Network for Organ Sharing allocation policy change, temporary mechanical circulatory support devices have been increasingly used as a bridge to heart transplant (BTT). The Impella 5.5 allows for higher flows, longer durations of support, and greater patient mobility, yet limited data exists regarding its use as BTT. We report our clinical outcomes using the Impella 5.5 to evaluate the feasibility and efficacy of providing durable and longer support to patients awaiting heart transplantation.

Methods: A single-center retrospective case series of adult patients who underwent Impella 5.5 placement as a BTT was conducted from 12/2019 to 07/2023. Analysis included baseline demographics, device complications, and post-transplant outcomes. The primary endpoints were survival to transplant and duration of support, tabulated over time. Device outcomes included stroke, arrhythmia requiring escalation of treatment, access site infection, vascular complications, and device migration or valve disruption. Post-transplant outcomes included length of stay, primary graft dysfunction, and mortality rates.

Results: 34 patients underwent Impella 5.5 placement as a BTT over the study period. The median age was 59 years, with 91% of patients presenting in acute decompensated heart failure. Prior to Impella 5.5 placement, 59% of patients were supported with IABP, while 9% were supported with an Impella CP. The median duration of Impella 5.5 support was 19 days, and the number of patients supported greater than 21 days increased over time (Figure 1). The maximum duration of support was 63 days. There were no waitlist mortalities. Three patients returned to OR for hematoma evacuation, while one patient developed a left subclavian pseudoaneurysm managed conservatively. 94% (n=32) were ambulatory over their waitlist period. Post-transplant, median length of stay was 12 days, and there were no incidences of moderate/severe primary graft dysfunction or 30-day mortalities.

Conclusions: Impella 5.5 appears to be an acceptable BTT strategy. All patients listed for heart transplant were successfully bridged with no waitlist mortalities and acceptable post-transplant outcomes. Despite increasing waitlist and support duration times, the rate of complications both during support and post-transplant remained low.

Table 1. Baseline Characteristics

Baseline Characteristics	Total N=34
Age, years, median (IQR)	59 (50-67)
Gender	
Male, n (%)	27 (79)
Female, n (%)	7 (21)
Ethnicity	
White, n (%)	16 (47)
Black, n (%)	10 (29)
Other, n (%)	8 (24)
BMI, kg/m ² , median (IQR)	26 (25-30)
Hypertension, n (%)	20 (59)
Peripheral Vascular Disease, n (%)	0
Cerebral Vascular Accident, n (%)	6 (18)
Diabetes, n (%)	11 (32)
Chronic Kidney Disease, n (%)	15 (44)
Dialysis, n (%)	3 (9)
Ejection Fraction, median (IQR)	15 (10-20)
Etiology of Cardiogenic Shock, n (%)	
Acute Myocardial Infarction	2 (6)
Acute Decompensated Heart Failure	31 (91)
Myocarditis	1 (3)
UNOS Status, n (%)	
1	5 (15)
2	29 (85)
Outside Hospital Transfer, n (%)	9 (26)
Inotrope dependence, n (%)	32 (94)
Ventilator dependence, n (%)	5 (15)
Functional Status before Impella 5.5, n (%)	
Bedbound	14 (41)
Ambulating	20 (59)
Mechanical circulatory support before Impella 5.5, n (%)	
Intra-aortic balloon pump	20 (59)
Impella CP	3 (9)
Impella CP + VA-ECMO	2 (6)
None	9 (26)
Organ Ischemia Time, minutes, median (IQR)	175 (126-196)
Cardiopulmonary Bypass Time, minutes, median (IQR)	114 (105-128)

UNOS: United Network for Organ Sharing; VA-ECMO: veno-arterial extracorporeal membrane oxygenation

Table 2. Device and Post-Transplant Outcomes

Device Outcomes	Total N=34
Days with Impella 5.5, median (IQR)	19 (11-25)
Method of Impella 5.5 removal, n (%)	
Removed during cardiectomy	32 (94)
Removed from axillary incision	2 (6)
Anatomic Location, n (%)	
Right Axillary	28 (82)
Left Axillary	5 (15)
Central	1 (3)
Vascular Complication, n (%)	
Hematoma/bleeding requiring OR	3 (9)
Dissection	0 (0)
Pseudoaneurysm	1 (3)
Limb Ischemia	0 (0)
Stroke, n (%)	0 (0)
Arrhythmia, n (%)	1 (3)
Access Site Infection, n (%)	0 (0)
Device Migration/Malpositioning, n (%)	0 (0)
Valve Disruption, n (%)	0 (0)
Pump Exchange, n (%)	0 (0)
Functional Status After Impella 5.5, n (%)	
Bedbound	2 (6)
Ambulating	32 (94)
Post-Transplant Outcomes	Total N=34
Moderate/Severe Primary Graft Dysfunction, n (%)	0 (0)
Postoperative MCS, n (%)	0 (0)
Stroke, n (%)	0 (0)
Acute Kidney Injury Requiring Dialysis, n (%)	2 (6)
ICU Length of Stay, days, median (IQR)	6 (4-10)
Postoperative Length of Stay, days, median (IQR)	12 (9-17)
Discharge Disposition, n (%)	
Home with Health Aid	13 (38)
Rehab Facility	21 (62)
30-Day Mortality, n (%)	0 (0)
90-Day Mortality, n (%)	1 (3)
1-Year Mortality, n (%)	1 (3)
Follow-up, days, median (IQR)	298.5 (180-534)

OR: Operating room; MCS: Mechanical circulatory support; ICU: Intensive care unit

CARC11

Immediate Hemodilution Following VA-ECMO Initiation: Implications for Treatment Response and Organ Functions in Cardiac Patients

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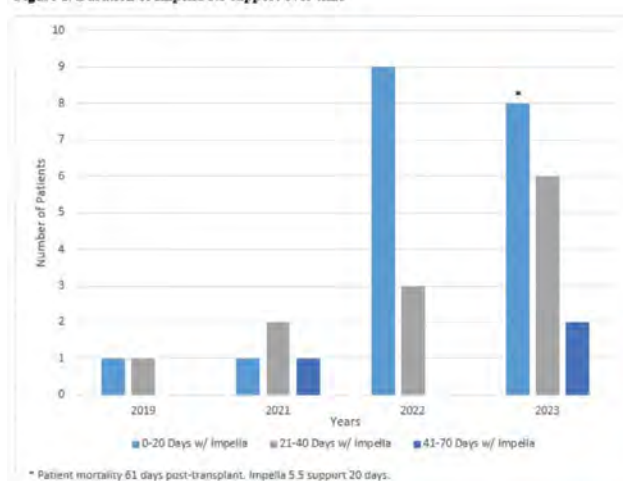
Background: A significant concern associated with venoarterial extracorporeal membrane oxygenation (VA-ECMO) technology pertains to the continuous rapid infusion of non-physiological priming fluid into the arteries, resulting in swift blood dilution and increased volume load. This study aimed to analyze the immediate hemodilution after VA-ECMO initiation and its effect on the subsequent treatment and changes in organ function.

Methods: We retrospectively screened and enrolled 50 patients who received VA-ECMO in the cardiology care unit between January 2019 and January 2023. Extrapolating from the fact that loss of 1/3 of the blood volume can cause shock, we hypothesized that decreasing the oxygen-carrying capacity of the blood by 30% [30% decrease of hematocrit (Hct) level] can exceed the compensatory mechanisms of human body and cause tissue ischemia. Those with a $\geq 30\%$ Hct decrease immediately after priming were assigned to the Hct^{Δ30%+} group, whereas the remaining were assigned to the Hct^{Δ30%-} group. Baseline characteristics, pre-ECMO laboratory values, receipt of intra-aortic balloon pump (IABP) and continuous renal replacement therapy (CRRT), blood transfusion, peak levels of biomarkers during VA-ECMO support were compared between the two groups.

Results: A total of 50 patients were included in this study, while 17 patients were assigned to the Hct^{Δ30%+} group. There were no significant differences in baseline characteristics and pre-ECMO laboratory values between the two groups. Within 20 minutes after VA-ECMO initiation, all 50 patients experienced significant reductions in Hct, hemoglobin, and red blood cells values compared to pre-cannulation levels (Figure 1), with Hct showing the most pronounced reduction. Compared to the Hct^{Δ30%-} group, the Hct^{Δ30%+} group required higher volumes of red cell suspensions (12 U vs 4 U, $P=0.004$) and fresh frozen plasma (4.4 U vs 1.75 U, $P=0.008$) during VA-ECMO support. Patients in the Hct^{Δ30%+} group were more likely to receive IABP (70.6% vs 36.4%, $P=0.036$), CRRT (64.7% vs 18.2%, $P=0.002$). The peaks of creatine kinase-myocardial band (63.2 ng/mL vs 9.1 ng/mL, $P=0.049$), aspartate aminotransferase (370.1 U/L vs. 64.6 U/L, $P=0.041$), and alanine aminotransferase (64.9 U/L vs. 34.4 U/L, $P=0.045$) levels in the Hct^{Δ30%+} group during VA-ECMO were greater than those in the Hct^{Δ30%-} group.

Conclusion: A rapid decrease in Hct exceeding 30% after VA-ECMO initiation indicates the need for timely blood transfusion treatment. For these patients, it is crucial to promptly consider the combined use of IABP or CRRT based on patient's condition to alleviate left ventricular afterload and systemic volume overload while reducing potential damage to cardiac, renal, and hepatic functions. A Hct decrease $\geq 30\%$ could serve as a valuable benchmark for guiding clinical treatment strategies.

Figure 1. Duration of Impella 5.5 support over time



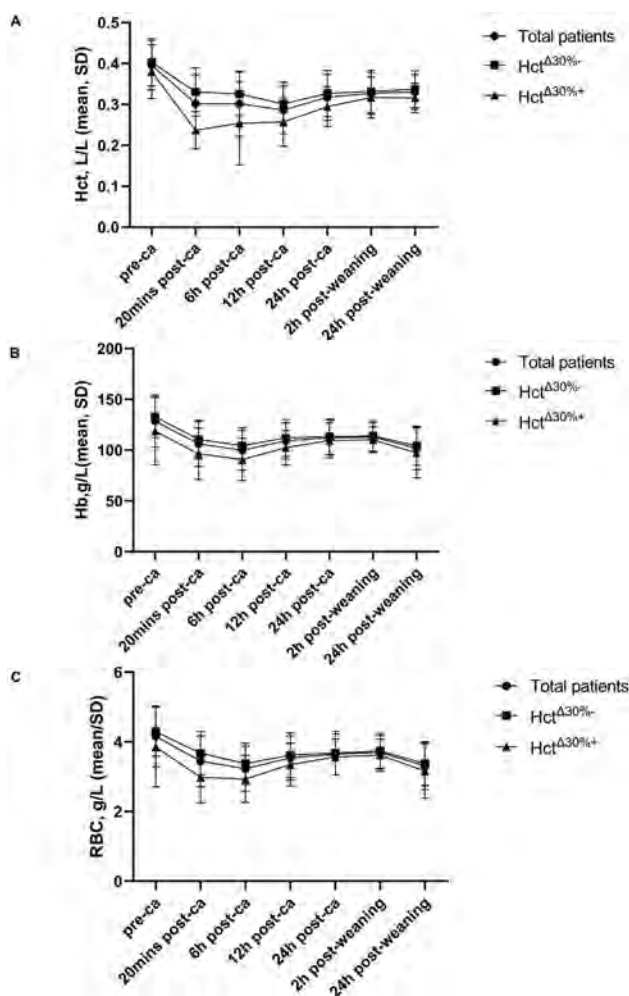


Figure 1. Changes in Hct, Hb, and RBC during VA-ECMO cannulation and weaning. A. Changes in the Hct value; B. Changes in the Hb value; C. Changes in the RBC value. ca: cannulation; Hct, hematocrit; Hb, hemoglobin; RBC, red blood cells; VA-ECMO: venoarterial extracorporeal membrane oxygenation.

CARC12

Bridge to Heart Transplant with Temporary Mechanical Circulatory Support: Trends and Waitlist Outcomes in the 2018 UNOS Policy Era

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Introduction: The 2018 UNOS heart allocation policy prioritizes patients receiving temporary mechanical circulatory support (tMCS) given the high waitlist morbidity and mortality. We analyzed national trends and waitlist outcomes for candidates receiving tMCS at the time of waitlisting before and after the UNOS allocation policy change.

Methods: Adult patients waitlisted for isolated heart transplantation before (5/13/14–10/18/18) and after (10/18/18–03/30/23) the UNOS policy change were included using the UNOS database. Analyzed tMCS modalities included extracorporeal membrane oxygenation (ECMO), intra-aortic balloon pump (IABP), and Impella. Baseline characteristics and the prevalence of tMCS modalities were compared with the Chi² and Mann-Whitney U tests. The primary outcome was 90-day incidence of waitlist mortality or delisting due to clinical deterioration and the secondary outcome was 90-day incidence of transplantation or delisting due to cardiac recovery. Primary and secondary outcomes were analyzed with multivariable Cox regression with competing outcomes adjusting for established predictors of waitlist mortality, including age, sex, heart failure etiology, creatinine, inotrope support, ventilator support and hemodynamic measurements.

Results: Among the 27,343 patients listed for heart transplantation during the study period (pre-policy change: 13,004 vs. post-policy change: 14,339), a total of 4,142 patients received tMCS at the time of waitlisting (Table 1). The prevalence of tMCS increased significantly following the policy change (Figure 1). IABP was the most common tMCS modality before and after the policy change, although the proportion of IABP and ECMO support within the tMCS cohort decreased significantly following the policy change whereas the use of Impella increased (Figure 1). The adjusted odds of 90-day mortality for tMCS patients was significantly lower in the new policy cohort (Figure 2A). Patients receiving ECMO support had the highest odds of 90-day mortality before and after the policy change (Figure 2B). Patients receiving tMCS had significantly higher adjusted odds of transplantation within 90-days of waitlisting following the policy change (Figure 3C), with patients on ECMO support having the highest adjusted incidence of transplantation within 90-days in the post-policy change cohort (Figure 3D).

Conclusion: The use of tMCS for bridge to heart transplantation increased 3-folds (7.4% to 22.2%) following the UNOS policy change. The proportional distribution of tMCS modalities shifted following the policy change, characterized by an increased use of Impella. Patients supported with tMCS have significantly lower odds of waitlist mortality and higher odds of transplantation within 90-days of waitlisting under the 2018 allocation system. Among tMCS modalities, ECMO is associated with the highest odds of 90-day waitlist mortality but also the highest incidence of transplantation within 90-days in the 2018 UNOS policy era.

Table 1. Patient characteristics at the time of waitlisting for patients receiving temporary mechanical circulatory support before and after the 2018 UNOS policy change.

Table 1. Patient characteristics at the time of waitlisting for patients receiving temporary mechanical circulatory support before and after the 2018 UNOS policy change

Feature	Pre-Policy Change	Post-Policy Change	p-value
Age, mean (SD)	39.0 (10.0)	38.0 (10.0)	0.727
Sex, n (%)			0.002
Male	188 (74.8%)	169 (76.8%)	
Female	65 (26.2%)	51 (23.2%)	
Diagnosis, n (%)			0.001
Aortic	100 (40.8%)	1,023 (57.2%)	
Mitral	248 (100.0%)	377 (209.8%)	
Tricuspid	31 (12.5%)	344 (192.2%)	
Pulmonary	48 (19.6%)	154 (86.5%)	
Other	1 (0.4%)	27 (15.3%)	
Cardiac	75 (30.8%)	377 (209.8%)	0.001
Aortic regurgitation	1,102 (452.2%)	1,102 (617.2%)	0.002
Aortic stenosis	127 (51.2%)	149 (83.2%)	
Mitral regurgitation	182 (74.8%)	256 (143.8%)	
Mitral stenosis	371 (150.8%)	1,126 (628.8%)	<0.001
Tricuspid regurgitation	498 (203.8%)	1,890 (105.2%)	
Tricuspid stenosis	248 (100.0%)	344 (192.2%)	
Pulmonary regurgitation	105 (43.3%)	365 (203.2%)	
Pulmonary stenosis	1 (0.4%)	27 (15.3%)	
Other	757 (303.4%)	1,102 (617.2%)	<0.001
Aortic regurgitation	117 (47.2%)	208 (116.8%)	<0.001
Aortic stenosis	117 (47.2%)	208 (116.8%)	<0.001
Mitral regurgitation	214 (87.2%)	377 (209.8%)	0.001
Mitral stenosis	31 (12.5%)	344 (192.2%)	0.001
Tricuspid regurgitation	248 (100.0%)	377 (209.8%)	0.001
Tricuspid stenosis	31 (12.5%)	344 (192.2%)	0.001
Pulmonary regurgitation	48 (19.6%)	154 (86.5%)	0.001
Pulmonary stenosis	1 (0.4%)	27 (15.3%)	0.001
Other	1 (0.4%)	27 (15.3%)	0.001
Aortic regurgitation	117 (47.2%)	208 (116.8%)	<0.001
Aortic stenosis	117 (47.2%)	208 (116.8%)	<0.001
Mitral regurgitation	214 (87.2%)	377 (209.8%)	0.001
Mitral stenosis	31 (12.5%)	344 (192.2%)	0.001
Tricuspid regurgitation	248 (100.0%)	377 (209.8%)	0.001
Tricuspid stenosis	31 (12.5%)	344 (192.2%)	0.001
Pulmonary regurgitation	48 (19.6%)	154 (86.5%)	0.001
Pulmonary stenosis	1 (0.4%)	27 (15.3%)	0.001
Other	1 (0.4%)	27 (15.3%)	0.001

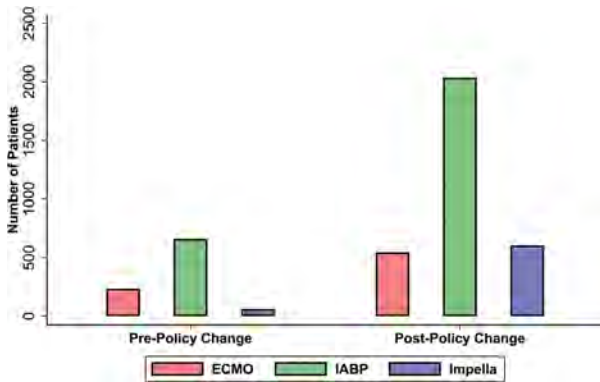


Figure 1. Use of temporary mechanical circulatory support before and after the 2018 UNOS policy change.

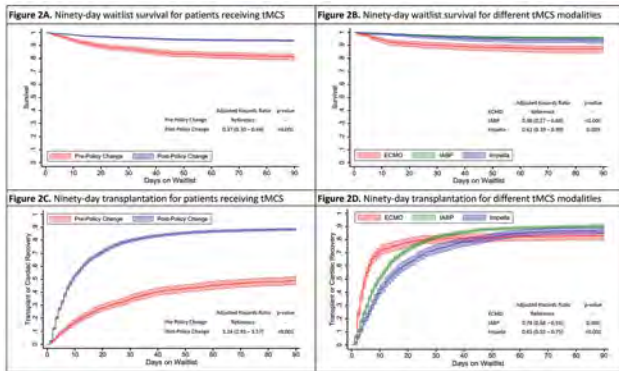


Figure 2. Ninety-day survival and transplant curves for patients receiving mechanical circulatory support at the time of waitlisting.

CARC13

Use Of Newer Intravascular Ambulatory Left Ventricular Assist Devices As A Bridging Strategy For Cardiogenic Shock In Adult Congenital Heart Disease Patients

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Background: Cardiogenic shock [CS], either de novo or post-cardiotomy [PCCS] is associated with high mortality. Suitable patients may be successfully bridged using newer intravascular ambulatory left ventricular assist devices [Impella 5.5, Abiomed, Danvers, MA] as a bridge to recovery or definitive therapy. We examined our outcomes in select adult congenital heart disease [ACHD] patients bridged with Impella 5.5.

Methods: Between January 2020 and June 2023, 92 patients underwent trans right-axillary artery placement of LV-Impella 5.5 for cardiogenic shock.

Within this cohort, there were 5 ACHD patients, 2 patients requiring post-cardiotomy support, and 3 patients requiring pre-transplant support, including 2 patients for reversal of pulmonary hypertension [PH]. Data was collected prospectively and analyzed retrospectively.

Results: Mean age was 39±10 years. There were 4 males and 1 female. In the 2 pre-transplant patients where it was placed for reversal of PH, this was noted within 30 days, from 10 to 2 Wood units [WU], and 4.8 to 2.5 WU respectively, making both imminently transplantable [Table-1]. Complications included renal replacement therapy and requirement for extra-corporeal membrane oxygenator support for primary graft dysfunction following heart transplantation in 1 patient. Planning with computerized tomographic imaging guided reconstruction and printing of a 3-dimensional model greatly facilitated impella placement in 1 patient with complex intra-cardiac anatomy [Figure]. Duration of Impella support was 26±23 days. Four patients were alive at 12±7.8 months. One death occurred in the PCCS group on the 5th postoperative day, due to liver failure from cirrhosis, bowel ischemia, and subsequent family request to withdraw support.

Conclusions: Our entire cohort includes a diverse patient population undergoing newer intravascular ambulatory LV assist device [Impella] 5.5 placement, and demonstrates low rate of adverse events combined with good survival benefit. Encouraged by our excellent results, we have been utilizing Impella 5.5 as a bridge to recovery post-cardiotomy or to transplantation in the adult congenital heart disease patients, with encouraging results. Reversal of pulmonary hypertension in the pretransplant cohort has enabled listing for transplantation and availability of a suitable heart within a short period of time as status 2 on the heart transplant waiting list.

Table 1.

Table-1: Reversal of pulmonary hypertension with Impella therapy pre-transplantation

	PAS	PAD	PAM	PCWP	TPG	PVR	RA	CI	CO	PA sat
P1 Baseline	80	50	60	38	22	10	22	1.1	2.2	34%
P1 Day-30 Impella	45	20	28	18	10	2	7	2.7	5	59%
P2 Baseline	88	50	64	41	23	4.8	18	3	4.7	58%
P2 Day-30 Impella	57	26	36	16	20	2.5	7	4	7.3	74%

PAS/D/M: pulmonary artery systolic/diastolic/mean pressures; PCWP: pulmonary capillary wedge pressure; TPG: trans pulmonary gradient; RA: right atrial pressure. All in mmHg. PVR: pulmonary vascular resistance in wood units CI: cardiac index in liters/minute/square meter body surface area; CO: cardiac output in liters/minute; PA sat: pulmonary artery oxygen saturation



Figure. 3-D printed model to facilitate Impella placement

CARC14

Impella 5.5 Bridge to Transplantation after HeartMate 3 Explantation for LVAD Endocarditis

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Background: Left ventricular assist device (LVAD) associated infections are a frequent complication requiring a combination of antibiotics, surgical debridement, pump exchange, or heart transplantation. We present a case of ascending driveline infection and eventual endocarditis managed with complete LVAD explant and Impella 5.5 insertion for bridge to transplantation.

Methods: A 41-year-old male underwent HeartMate 3 (Abbott, Chicago, IL) implantation via bilateral thoracotomies in October 2021. He presented 21 months post-operatively with methicillin susceptible *Staph aureus* (MSSA) driveline infection and bacteremia. He underwent drainage of the driveline infection and was discharged on cefazolin indefinitely.

Four months later he presented with MSSA and *Bacillus cereus* bacteremia. Imaging demonstrated a fluid collection around the outflow graft and hypermetabolic activity throughout the pump pocket and outflow graft. On initial presentation, the patient was not a candidate for heart transplantation and it was felt that he would not tolerate an LVAD explant. The bacteremia cleared with intravenous antibiotics; however, one month later he developed recurrent fever, splenic infarcts and pseudoaneurysm requiring embolization. Despite persistent infection, his overall clinical status had improved and he underwent LVAD explant with Impella 5.5 placement.

Extensive mediastinal dissection was performed. An abscess cavity around the outflow graft and in the pump pocket were drained. The LVAD, apical ring, and driveline were removed. The ventriculotomy was repaired in three layers using 4-0 Prolene mattress sutures, autologous pericardial pledgets, and bovine pericardial patch. Due to the friability of the aortic tissue, a 5 mm stump of outflow graft was left on the aorta. The field was repeatedly irrigated with antibiotic saline and Phase One solution. All intraoperative gram stains were negative for organisms.

An Impella 5.5 was placed while the chest remained open in case of apical injury. The patient was weaned from cardiopulmonary bypass and fully supported with Impella 5.5. Although no significant bleeding was encountered, it was elected to temporarily pack the chest and he underwent uneventful closure two days later.

Results: The initial postoperative course was unremarkable with no bleeding or hemodynamic complications. He has no evidence of ongoing infection. He is able to ambulate and pre-habilitate without difficulty. The patient remains well-supported on Impella 5.5 awaiting heart transplant.

Conclusion: Cardiac transplant or LVAD pump exchange are common strategies for the treatment of deep LVAD infection, however, in the case of extensive infection, the risk of mediastinitis after transplant or recurrent device infection after pump exchange remains high. We demonstrate that infected patients can safely undergo LVAD explant with temporary Impella 5.5 support for continued antibiotic therapy and staged transplantation.

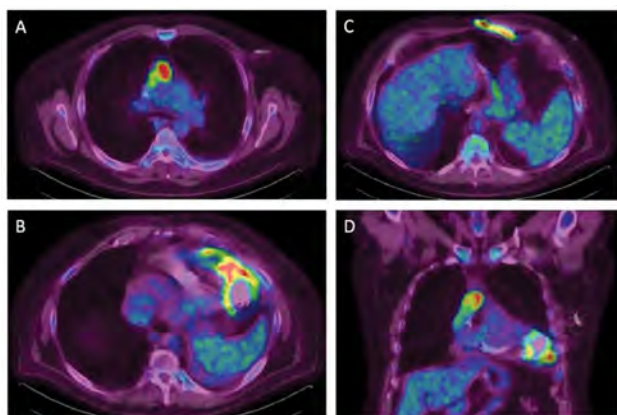


Figure One: Pre-Operative PET Imaging showing hypermetabolic activity around the (A) distal outflow graft and aorta, (B) pump pocket and proximal outflow graft, (C) driveline, and (D) in coronal section.

Figure 1. Pre-Operative PET Imaging showing hypermetabolic activity around the (A) distal outflow graft and aorta, (B) pump pocket and proximal outflow graft, (C) driveline, and (D) in coronal section.



Figure Two: (A) Pre-bypass dissection of the outflow graft and pump pocket and (B) unlocking the LVAD from apical ring on bypass. Images are oriented from surgeon's point of view with patient's head to image left.

Figure 2. (A) Pre-bypass dissection of the outflow graft and pump pocket and (B) unlocking the LVAD from apical ring on bypass. Images are oriented from surgeon's point of view with patient's head to image left.

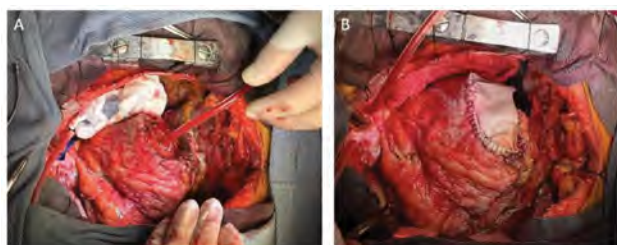


Figure Three: (A) Left ventriculotomy after pump and ring removal with vent in place and (B) Most superficial of three layer closure with bovine pericardial patch reinforcement. Images are oriented from surgeon's point of view with patient's head to image left.

Figure 3. (A) Left ventriculotomy after pump and ring removal with vent in place and (B) Most superficial of three layer closure with bovine pericardial patch reinforcement. Images are oriented from surgeon's point of view with patient's head to image left.

CARC15

Coronary Artery Bypass Grafting for Ischemic Cardiomyopathy: Improved Survival in the Current Era

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Objective: Coronary artery bypass grafting (CABG) is a proven treatment for patients with ischemic cardiomyopathy (ICM) and depressed ejection fraction (EF <35%). However, selecting CABG as first-line treatment in an expanding era of advanced heart failure therapies is often difficult. Our strategy has increasingly incorporated planned perioperative mechanical circulatory support (MCS) by way of Impella or intra-aortic balloon pump (IABP) in these high-risk patients. This report evaluates the perioperative utilization of MCS in CABG patients with ICM and depressed EF <35%, and the subsequent impact on long-term survival.

Methods: This is a retrospective study from a comprehensive heart center evaluating perioperative and long-term survival in 288 patients with ICM and EF <35% who underwent isolated CABG between July 2014 and August 2022. Patients were stratified into three cohorts: Postop IABP (N=56), Postop Impella (N=62), and No MCS (N=170). The primary outcomes were 5-year survival, obtained from death claims contained within the Optum national database, and overall long-term survival, evaluated using Kaplan-Meier (KM) estimates of the entire cohort as well as each group. Secondary outcomes included perioperative morbidity and 30-day mortality.

Results: The mean age was 65.2 years and the median follow-up was 5.25 years (Table 1). The STS predicted perioperative mortality was highest in the Postop IABP group (3.17%) compared to Postop Impella (1.58%) and No MCS (1.44%) [$p < 0.001$]. Both Postop IABP and Postop Impella groups had a significantly lower preoperative EF compared to No MCS (25% vs 30%, $p < 0.001$). Operatively, the Postop Impella group had more grafts per case versus Postop IABP and No MCS (4 vs 3 vs 3, $p < 0.001$), with associated longer cardiopulmonary bypass times (132 vs 105 vs 108 minutes, $p < 0.001$) and cross-clamp times (102 vs 85 vs 83 minutes, $p < 0.001$). 5-year survival was 85% for the entire cohort, with the best 5-year survival (94%) achieved in Postop Impella (Table 1). KM analysis demonstrated favorable 8-year long-term survival of the entire cohort at 83.3% (Figure 1). KM analysis between the groups demonstrated significantly decreased late survival in Postop IABP compared to Postop Impella (72.6% vs 93.5%, $p = 0.012$) and No MCS (72.6% vs 83.8%, $p = 0.029$) (Figure 2). Perioperative stroke (4% vs 5% vs 3%, $p = 0.753$) and atrial fibrillation (27% vs 34% vs 22%, $p = 0.202$) were not different between groups, while the incidence of renal failure was higher in Postop IABP and Postop Impella (5% vs 5% vs 0%, $p < 0.005$).

Conclusions: In the current era, long-term survival after CABG for patients with ICM and EF <35% is good, and the use of perioperative MCS with Impella in the most critically ill patients may allow for more complete revascularization and improved late survival compared to IABP. Long-term survival is feasible in these high-risk patients, and CABG should be considered before committing to other advanced heart failure therapies.

Table 1. Postoperative Characteristics and Outcomes

Postoperative Characteristics	Total (n=288)	Periop IABP (n=56)	Periop Impella (n=56)	No MCS (n=176)	p value
Age (years), mean ± SD	65.2 ± 10.83	66.07 ± 12.38	62.56 ± 9.29	65.08 ± 10.7	0.001
Sex, n (%)					0.121
Male	246 (85)	44 (78)	37 (66)	145 (82)	
Female	42 (15)	12 (22)	19 (34)	31 (18)	
Race, n (%)					0.119
White	188 (65)	29 (52)	34 (61)	81 (46)	
African American	72 (25)	13 (23)	9 (16)	34 (19)	
Other	28 (10)	13 (23)	13 (23)	21 (12)	
BMI, median (IQR)	28.8 (25.1-33.0)	28.65 (23.52-33.06)	27.3 (24.35-30.97)	27.15 (24.02-30.92)	0.105
Hypertension, n (%)	280 (97)	51 (91)	58 (100)	153 (87)	0.973
Hyperlipidemia, n (%)	254 (88)	45 (80)	58 (100)	151 (86)	0.078
Diabetes, n (%)	177 (61)	37 (66)	29 (52)	101 (58)	0.651
Smoking, n (%)	87 (30)	15 (27)	17 (30)	37 (21)	0.424
Renal Dysfunction, n (%)	78 (27)	15 (27)	17 (30)	46 (26)	0.007
Stroke, n (%)	20 (7)	3 (5)	4 (7)	13 (7)	0.931
Bleeding Cerebral, median (IQR)	1.0 (0.5-1.4)	1.0 (0.5-1.4)	0.8 (0.4-1.3)	1.0 (0.6-1.3)	0.332
Epistaxis, median (IQR)	26.3 (20-31)	29 (20-30)	23 (20-29)	30 (21-37)	< 0.001
NYHA Class, n (%)					
1	31 (11)	9 (16)	9 (16)	21 (12)	0.136
2	80 (28)	10 (18)	11 (20)	59 (33)	0.02
3	83 (29)	17 (30)	13 (23)	49 (28)	0.04
4	29 (10)	4 (7)	4 (7)	14 (8)	0.027
STS Mortality Risk, median (IQR)	1.72 (0.94-3.39)	1.17 (0.68-3.03)	1.58 (0.99-3.97)	1.44 (0.76-4.3)	< 0.001
Left Ventricular End Diastolic Diameter, cm, median (IQR)	5.2 (4.8-5.5)	5.1 (4.5-5.4)	5.4 (5-6)	5.2 (4.8-5.6)	0.003
Left Ventricular End Systolic Diameter, cm, median (IQR)	4.3 (3.7-4.8)	4.1 (3.4-4.6)	4.4 (3.8-5.1)	4.2 (3.6-4.8)	0.067
Previous Percutaneous Coronary Intervention, n (%)	87 (30)	18 (32)	17 (30)	50 (28)	0.823
Left Main Disease >50%, n (%)	92 (32)	26 (46)	19 (34)	50 (28)	0.037
Care Setting, n (%)					< 0.001
Elective	190 (66)	31 (55)	17 (30)	70 (40)	
Urgent/Emergent	198 (69)	25 (45)	41 (73)	81 (46)	
Peroperative Mechanical Circulatory Support, n (%)					< 0.001
Intra-aortic Balloon Pump	43 (15)	31 (55)	12 (21)	2 (1)	
Impella	2 (1)	0 (0)	0 (0)	0 (0)	
Cardiopulmonary Bypass Time, minutes, median (IQR)	115 (64-132)	65 (64-127)	132 (115-148)	109 (83-128)	< 0.001
Cross-clamp Time, minutes, median (IQR)	64 (71-101)	83 (73-95)	62 (59-120)	63 (66-98)	< 0.001
Total Grafts, n, median (IQR)	3 (1-4)	3 (1-4)	4 (3-5)	3 (1-4)	< 0.001
Proximal Anastomosis, n, median (IQR)	36 (14-60)	31 (15-50)	50 (33-56)	56 (31-66)	< 0.001
Outcomes					
Postoperative Stroke, n (%)	10 (3)	2 (4)	3 (5)	5 (3)	0.513
Postoperative Atrial Fibrillation, n (%)	54 (19)	13 (23)	17 (30)	24 (14)	0.301
Postoperative Renal Failure requiring Dialysis, n (%)	8 (3)	3 (5)	3 (5)	2 (1)	0.003
Mortality, n (%)					
30-day mortality	7 (2)	3 (5)	4 (7)	3 (2)	0.007
1-year mortality	21 (7)	9 (16)	4 (7)	8 (5)	0.022
5-year mortality	41 (14)	17 (30)	4 (7)	24 (14)	0.007

IABP: Intra-aortic balloon pump; NYHA: New York Heart Association; STS: Society of Thoracic Surgeons; BMI: Body mass index; IQR: Interquartile range; MCS: Mechanical circulatory support.

CARC16

Biomechanical Analysis of a Novel Sternal Closure Device

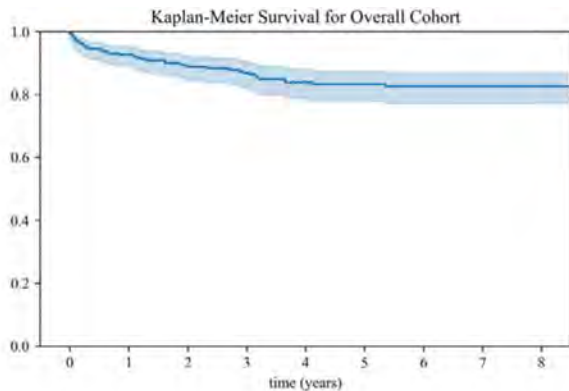
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Purpose of Study: The most common means of sternal closure after sternotomy is stainless steel wire cerclage. These wires, while inexpensive and simple in design, are known to be associated with low strength closure and risk for sternal dehiscence. We have designed and developed a novel sternal closure device which is built upon the stainless-steel wire platform, but which uses polymer grommets at the sternal interfaces to distribute load over a large surface area of bone. This is assumed to mitigate erosion of wire through bone and increase closure strength (Figure 1). In this biomechanical analysis we analyzed the tensile strength of single sternal wires, double sternal wires, and the novel sternal closure device.

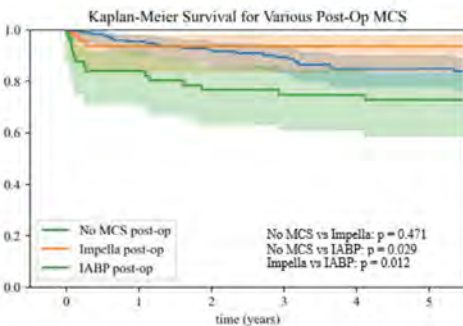
Methods: 6 samples of each closure device were installed in a bone model, with density of 0.16g/cm³ and modulus of 2.1 MPa in tension, which mimics the mechanical properties of osteoporotic human bone, and were loaded into an Instron tensile testing system. Force and displacement were continuously measured while the constructs were distracted at a rate of 10mm/min. Data were measured at 500 Hz and were exported to JMP Pro V. 17.2 for statistical analysis.

Results: The novel sternal closure device resulted in significantly greater forces and construct stiffness at all measured displacements, when compared to both double wires and single wires (Figure 2). The average stiffness of the standard sternal wire between 0 mm and 2 mm of displacement was 10.13 ± 2.61 mm/N compared to 46.90 ± 7.88 mm/N for the novel sternal closure device, a 4.6-fold improvement (Table 1).

Summary: The use of a novel sternal closure device which incorporates features designed to distribute the force of a wire cerclage over a larger surface of bone results in a stiffer sternal closure construct. This novel device demonstrated higher allowable loads at comparable displacement values as well as reduced wire erosion. In addition to these benefits, the design of the device permits rapid installation and low cost of production. This is in contrast to sternal plates, which confer a rigid closure, but are expensive and time consuming to install. Clinical use of this novel device may result in meaningful reduction in complications associated with the use of standard sternal wires such as sternal separation and fracture.



No. at Risk									
Overall	288	253	209	181	153	127	86	61	26



No. at Risk						
No MCS post-op	170	161	140	122	103	89
Impella post-op	62	47	28	21	14	5
IABP post-op	56	47	43	40	38	35



CARC17

Del Nido vs Conventional Cardioplegia: A Comparative Meta-Analysis of Operative and Postoperative Outcomes in Adult Cardiac Surgery

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Background: Cardioplegia, a key element of cardiac surgery, has evolved with the introduction of Del Nido cardioplegia, which provides extended myocardial protection. However, the comparative efficacy of Del Nido and conventional cardioplegia remains a topic of debate. This study aims to compare the operative and postoperative effects of Del Nido and conventional cardioplegia in cardiac surgery.

Methods: We performed a literature search of PubMed, Embase, and Scopus until April 2023 for studies comparing Del Nido and conventional cardioplegia, focusing on key operative and postoperative outcomes. These outcomes, both continuous and dichotomous, were assessed using Mean Difference (MD) and Odds Ratio (OR), respectively. Analysis was done using R (version 4.0.3) using metafor and meta packages.

Results: Our analysis incorporated 36 studies with 21429 patients (8350 in the Del Nido group and 13079 in the conventional group). For operative outcomes, Del Nido cardioplegia showed a significant reduction in aortic cross-clamp time (MD -6.68 min; 95% CI -10.28 to -3.09, $P<0.01$, $I^2=96\%$) and cardioplegia volume (MD -1223.44 mL; 95% CI -1472.21 to -974.66, $P<0.01$, $I^2=99\%$). For perioperative outcomes, there were no significant differences between the two groups in troponin T levels (MD -0.11 ng/mL; 95% CI -0.26 to 0.05, $P=0.18$, $I^2=98\%$), CK-MB (MD -1.60 ng/mL; 95% CI -4.49 to 1.29, $P=0.28$, $I^2=79\%$), mechanical ventilation time (MD -0.54 hours; 95% CI -1.22 to 0.12, $P=0.11$, $I^2=69\%$), length of ICU stay (MD -0.14 days; 95% CI -0.34 to 0.06, $P=0.17$, $I^2=73\%$), and length of hospital stay (MD 0.01 days; 95% CI -0.25 to 0.26, $P=0.96$, $I^2=36\%$). In terms of major events, there were no significant differences in perioperative mortality (OR 0.97; 95% CI 0.70 to 1.34, $P=0.86$, $I^2=0\%$), atrial fibrillation rate (OR 0.99; 95% CI 0.77 to 1.27, $P=0.96$, $I^2=67\%$), and myocardial infarction (OR 1.23; 95% CI 0.74 to 2.04, $P=0.42$, $I^2=0\%$) between the Del Nido and conventional cardioplegia groups.

Conclusions: Del Nido cardioplegia may offer operative benefits over conventional cardioplegia, while postoperative outcomes remain similar. Further high-quality studies are necessary to confirm these findings, underlining the importance of continued exploration in this area of cardiac surgery.

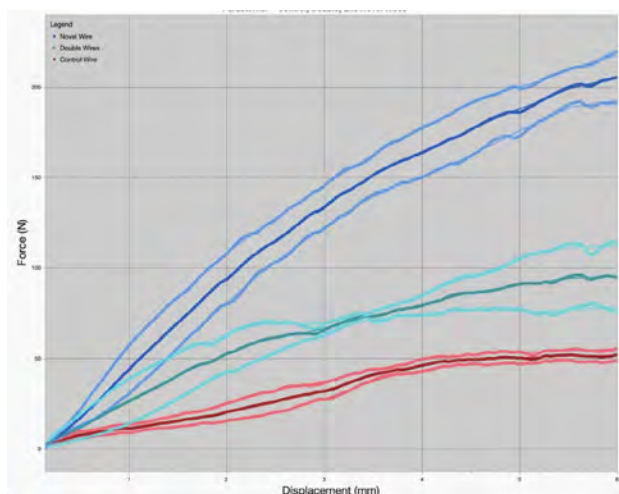


Table 1.

	Standard Sternal Wires	Novel Sternal Closure	p-value
Stiffness - 0-2mm (N/mm)	10.1±2.6	46.9±7.9	<0.001
Stiffness- 2-4mm (N/mm)	11.5±0.8	41.8±3.8	<0.001
Stiffness- 0-4mm (N/mm)	12.9±3.4	34.7±9.5	<0.001
Load at 2mm (N)	20.3±5.5	95.6±13.9	<0.001
Load at 4mm (N)	46.2±2.9	164.9±12.3	<0.001

CARC18

Characterizing Survival for Patients Supported with Inotropes after the 2018 Donor Allocation Restructuring: A UNOS Database Analysis

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Background: We sought to characterize adaptive changes to the revised UNOS donor heart allocation policy in 2018 and estimate long-term survival trends for heart transplant (HTx) recipients with respect to inotropic support.

Methods: Patients listed for HTx between 10/18/2016 and 9/30/2021 were identified from the UNOS database and stratified into pre- and post-policy revision groups. Sub-analyses were then performed to examine trends in device progression where a patient that is listed on inotropes is later transplanted on inotropes and/or on extracorporeal membranous oxygenator (ECMO), durable left ventricular assist device (LVAD), temporary mechanical circulatory support (tMCS), or intra-aortic balloon pump (IABP). Survival data post-HTx were calculated and plotted.

Results: Overall, 5,863 patients were transplanted (Pre: 3,006, Post: 2,857). Patient demographics differed by race, BMI, mean pulmonary artery pressure, mean PCWP, ventilatory support, and time on the waitlist (Table 1). Policy revisions were associated with an increase in patients transplanted supported with inotropes ($p<0.01$), ECMO ($p<0.01$), tMCS ($p<0.01$), and IABP ($p<0.01$). In contrast, policy revisions were associated with less patients transplanted with an LVAD ($p<0.01$) (Table 2). After the policy revision, 60.9% patients progressed from inotropes to another form of support as compared to only 35.6% pre-policy ($p<0.01$) (Table 3). Patients in the post-policy period were less likely to be removed from the waitlist (96.4% vs 99.8%, $p<0.01$) but more likely to survive (mortality 9.1% post-policy vs 18% pre-policy, $p<0.01$) (Table 4).

Conclusions: Allocation policy revisions have contributed to increased utilization of temporary support (inotropes, ECMO, tMCS, and IABP) and decreased utilization of others such as durable LVADs. Allocation policy changes have resulted in improved survival but decreased removal from the waitlist.

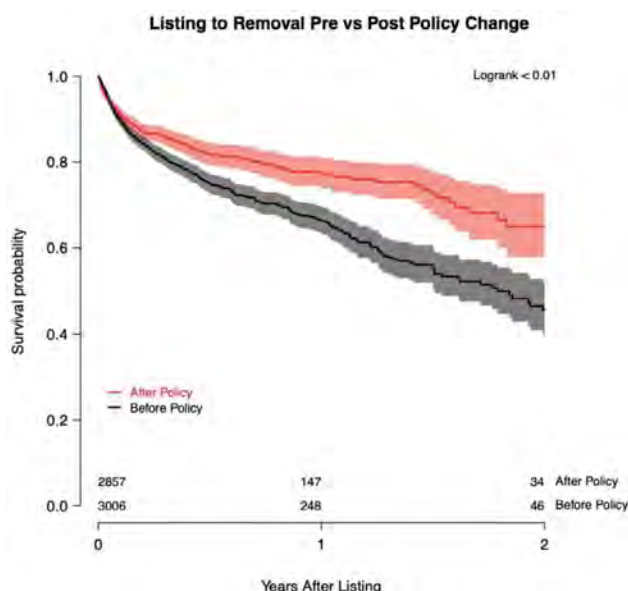


Figure 1. Survival while on the waitlist for patients listed before and after the policy change

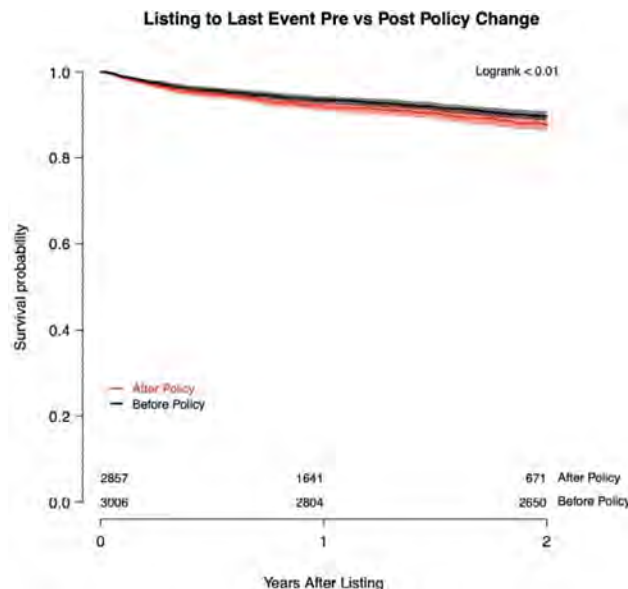


Figure 2. Survival for waitlisted patients listed before and after the policy change

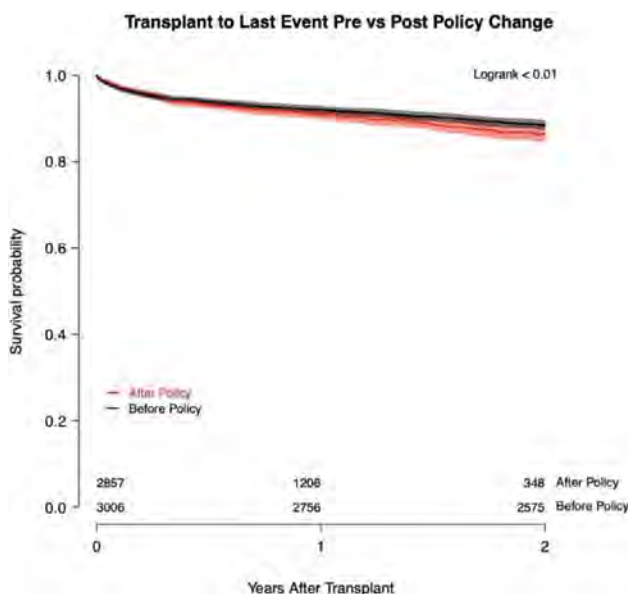


Figure 3. Survival for transplanted patients listed before and after the policy change

CARC19

Center Volume Substantially Influences Survival Following Donation After Circulatory Death Heart Transplantation

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Background: No prior studies have examined the association between center volume and post-transplant survival in donation after circulatory death (DCD) heart transplantation. This study evaluates the impact of center case volume on outcomes following isolated DCD heart transplantation.

Methods: The UNOS registry was queried to analyze adult recipients who underwent isolated DCD heart transplantation from 1/1/2019 to 9/30/2022. Low (≤ 6 cases), intermediate (7-19 cases), and high (≥ 20 cases) center volume designations were assigned based on the threshold regression. Baseline recipient, donor, and transplant characteristics were compared among the groups. Primary outcomes were post-transplant 1-year survival and complication rates. Multivariable Cox regression was performed to assess risk-adjusted hazards of center volume on 1-year post-transplant mortality.

Results: A total of 501 isolated DCD heart transplants were performed at 35 centers in the United States during the study period. 321 patients (64.1%), 104 patients (20.7%), and 76 patients (15.2%) underwent transplantation at high, intermediate, and low volume centers, respectively (Figure A). The recipients from high volume centers had shorter waitlist days, longer donor hospital distances, and lower rates of intensive care unit admission at the time of transplantation, waitlist blood transfusion, pre-transplant inotropic support, and bridge to transplantation with intra-aortic balloon pump compared to the recipients from intermediate and low volume centers (all, $p > 0.05$). The high and intermediate volume centers had significantly improved 30-day (high: 97.8% vs intermediate: 99.0% vs low: 96.1%), 90-day (high: 96.6% vs intermediate: 96.2% vs low: 92.1%), and 1-year (high: 93.7% vs intermediate: 95.1% vs low: 85.2%) post-transplant survival compared to the low volume centers (Figure B). The rates of post-transplant dialysis, stroke, permanent pacemaker insertion, acute rejection requiring medical therapy, and hospital length of stay were comparable among the groups (all, $p > 0.05$). When adjusting for established predictors of post-transplant mortality, the high volume centers (HR 0.42, CI 0.19-0.91, $p = 0.028$) had a significantly reduced risk of 1-year mortality compared to the low volume centers, but the intermediate volume centers (HR 0.35, CI 0.12-1.05, $p = 0.062$) had a similar risk of 1-year mortality compared to the low volume centers (Table).

Conclusion: The present study underscores the significance of center experience in DCD heart transplantation, where a lower case volume is associated with worse post-transplant survival.

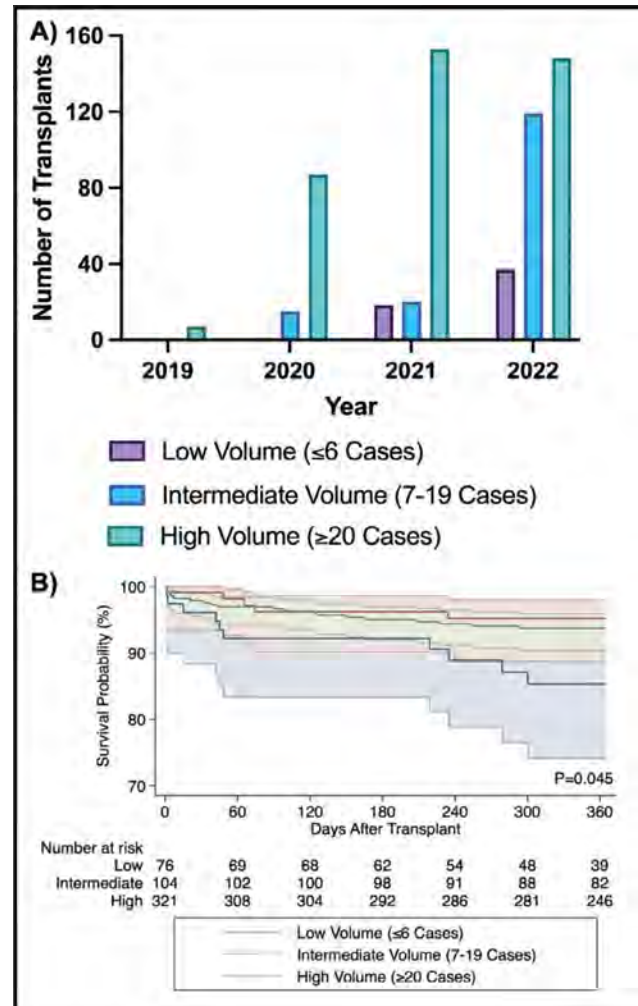


Figure 1. A) Total annual number and distribution of patients undergoing isolated DCD heart transplantation stratified by center volume. **B)** Kaplan-Meier estimates with 95% confidence intervals for survival following isolated DCD heart transplantation stratified by center volume.

Table 1. Multivariable Cox regression models for 1-year mortality following donation after circulatory death heart transplantation.

	Hazard Ratio	95% Confidence Interval	P-value
Center volume			
Low (≤ 6 cases)	Ref	Ref	Ref
Intermediate (7-19 cases)	0.35	0.12, 1.05	0.062
High (≥ 20 cases)	0.42	0.19, 0.91	0.028
Recipient age, increasing, per year	1.02	0.99, 1.05	0.222
Prior cardiac surgery	2.47	1.20, 5.08	0.014
Total graft ischemia time, increasing, per hour	1.14	0.99, 1.33	0.076
Donor age, increasing, per year	1.01	0.96, 1.05	0.794

3 (0.6%) study patients were excluded from the final model due to incomplete data.

CARC20

Older Donors Are Not Out Of Reach With Moderate Hypothermic Organ Preservation

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Purpose: The growing population of patients with advanced heart failure has increased the demand for heart transplant and the need to grow the donor pool, including using hearts from donors older than 50 years old. We present here a subgroup analysis of outcomes in recipients receiving hearts from older donors in the GUARDIAN-Heart Registry.

Methods: The GUARDIAN-Heart registry is the largest multicenter registry assessing the impact of organ preservation methods on heart transplant outcomes. A retrospective review of clinical outcomes in the subgroup of transplant recipients receiving hearts from donors over 50 years old were examined using summary statistics.

Results: A total of 62 heart transplant recipients with organs from donors older than 50 years were included in this analysis, N=24 transported in an Ice cooler, N=38 preserved using the SherpaPak System. Average ischemic times were 3.2 hours for ice and 3.6 hours for SherpaPak (see Table 1). Post-transplant, the need for mechanical circulatory support was meaningfully reduced in the SherpaPak cohort (33.3% ice vs 10.5% SherpaPak, p = 0.060). Although the rate of severe PGD post-transplant was reduced by over 50% (12.5% ice vs 5.3% SherpaPak), the result was not statistically significant. However, moderate to severe right ventricular dysfunction within 24 hours of transplant was significantly reduced in the SherpaPak cohort (31.8% ice vs 5.7% SherpaPak, p = 0.024). This may have contributed to a decreased ICU stay (15.0 days ice vs 7.4 days SherpaPak) and total hospital stay (34.4 days ice vs 22.1 days SherpaPak) although not statistically significant. Survival was similar among the groups. See Table 2.

Conclusions: In this high-risk cohort with older donor patients and average ischemic times in excess of 3.5 hours, use of the SherpaPak CTS results in significant improvements in post-transplant right heart function and might contribute to decreased ICU and hospital length of stay.

Table 2. Post-transplant outcomes in patients receiving hearts from older donors (>50 years old).

	ICE	SherpaPak	
	N = 24	N = 38	P-value
All post-transplant MCS	8/ 24 (33.3%)	4/ 38 (10.5%)	0.060
Time to wean from CPB	67.3 ± 51.6	41.7 ± 46.3	0.056
PGD	4/ 24 (16.7%)	2/ 38 (5.3%)	0.30
PGD Severe	3/ 24 (12.5%)	2/ 38 (5.3%)	0.59
Moderate/Severe RVD	7/ 22 (31.8%)	2/ 35 (5.7%)	0.024
Days of Inotrope use	16.0 ± 30.2	8.8 ± 5.3	0.26
Total ICU days	15.0 ± 34.5	7.4 ± 5.0	0.30
Total hospital stay (days)	34.4 ± 68.1	22.1 ± 14.2	0.39
In-hospital Survival	24/ 24 (100.0%)	37/ 38 (97.4%)	>0.99

Abbreviations: ICU = intensive care unit; MCS = mechanical circulatory support; PGD = primary graft dysfunction; RVD = right ventricular dysfunction.

Table 1. Baseline characteristics in patients receiving hearts from older donors (>50 years old).

	ICE	SherpaPak	
	N = 24	N = 38	P-value
Donor Age (years)	53.4 ± 2.8	54.1 ± 2.2	0.33
Donor BMI (kg/m ²)	28.4 ± 6.5	28.3 ± 4.8	0.96
Donor LVEF (%)	53.4 ± 2.8	54.1 ± 2.2	0.33
Distance to organ (miles)	262 ± 289	359 ± 353	0.24
Total ischemic time (hours)	3.2 ± 0.88	3.6 ± 0.98	0.08
F/M mismatch	3/ 24 (12.5%)	8/ 38 (21.1%)	0.61
Most undersized (<-15%)	5/ 24 (20.8%)	9/ 38 (23.7%)	>0.99
Recipient Age (years)	59.6 ± 7.3	61.7 ± 8.1	0.30
Recipient BMI (kg/m ²)	26.7 ± 4.3	28.5 ± 4.1	0.11
Waitlist Days	284 ± 486	118 ± 217	0.13
LVEF at Baseline (%)	18.5 ± 6.8	24.0 ± 12.2	0.026
Implantable VAD	10/ 24 (41.7%)	10/ 38 (26.3%)	0.33
Temporary IABP	5/ 24 (20.8%)	7/ 38 (18.4%)	>0.99
Temporary VAD/ECMO	1/ 24 (4.2%)	2/ 38 (5.3%)	>0.99

Abbreviations: BMI = body mass index; ECMO = extracorporeal membrane oxygenation; F/M mismatch = female to male mismatch; IABP = intra-aortic balloon pump; LVEF = left ventricular ejection fraction; MCS = mechanical circulatory support; VAD = ventricular assist device.

CARC21

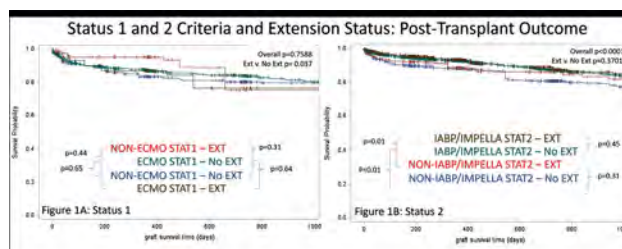
UNOS 2018 Heart Allocation Policy: Evaluation of Status 1 and 2 Extensions on Heart Transplant Outcomes

Toyokazu Endo, Michele Gallo, Erin Schumer, Siddharth Pahwa, Mark S. Slaughter, Jaimin R. Trivedi; *Department of Cardiothoracic Surgery, University of Louisville, Louisville, Kentucky, United States*

Background: United Network of Organ Sharing (UNOS) revised the heart allocation policy in 2018. In this study, we evaluated the outcomes based on temporary mechanical circulatory support devices and extension status among status 1 and 2 patients.

Methods: UNOS database was used to identify adult patients (age>17) listed for heart transplant as Status 1 or 2 from October 2018 to June 2023. Status 1 patients were divided into four groups according to those with veno-arterial extracorporeal membrane oxygenation (ECMO v. No ECMO) and extension status (Ext v. No Ext). Status 2 patients were also divided into four groups according to those with intra-aortic balloon pump or endovascular percutaneous support device (TMCS2 v. No TMCS2) and extension status (Ext v. No Ext). Status extension was defined as >7 days on status 1 with ECMO and >14 days on status 2 with TMCS2. Primary objective was to evaluate post-transplant outcomes. Secondary objective was to evaluate waitlist outcomes. Univariate analysis, Chi-squared test, and log-rank test was used to compare patient characteristics and outcomes within the group (alpha = 0.05).

Results: Total of 2025 were in status 1 (497 (25%) No ECMO No Ext v. 195 (10%) No ECMO Ext v. 1194 (50%) ECMO No Ext v. 139 (7%) ECMO Ext) and 10,454 were in status 2 (1401 (13%) No TMCS2 No Ext v. 699 (7%) No TMCS2 Ext v. 6675 (64%) TMCS2 No Ext v. 1679 (16%) TMCS2 Ext). Age, gender, race and etiology varied across all groups (p<0.05). Overall, waitlist survival was better in patients in status 1 with no extension (p<0.01), but survival did not differ based on extension status in status 2 patients (p=0.76). Patients on ECMO (status 1) with extension had better waitlist survival compared to those without (ECMO: Ext v. No Ext p=0.04), and patients with TMCS2 (status 2) with extension had better waitlist survival as well (TMCS2: Ext v. No Ext p=0.03). Overall, status 1 patients without extension had better post-transplant outcomes (Status1: No Ext v. Ext, p=0.03), while post-transplant outcome did not differ within status 2 patients (Status 2: No Ext v. Ext, p=0.37). Post transplant outcome did not differ within our study groups for status 1 (p=0.76) but did differ in status 2 (p<0.01). Within Status 2, No TMCS2 No Ext group had the worst post-transplant outcome (p<0.01) but TMCS usage was associated with better post-transplant outcome in status 2 patients (p<0.01). Extension status did not make a difference in patients with or without TMCS (No TMCS2 No Ext v. No TMCS2 Ext, p=0.31, TMCS2 No Ext v. TMCS2 Ext, p=0.45), **Conclusion:** 10% of patients with ECMO received extension in status 1, and 20% of patients with TMCS received extension in status 2. Extension status did not improve post-transplant outcomes but did improve waitlist outcomes in those with ECMO in status 1 and TMCS in status 2. UNOS heart allocation policy and extension status should be reconsidered in those with temporary mechanical circulatory support devices.



CARC22

Safety and Efficacy of Utilizing Organ Care System Heart in Combined Heart-Kidney Transplants

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Background: The Organ Care System (OCS) (Transmedics, Andover, MA) represents the only ex-vivo normothermic perfusion system by which a donor heart can be maintained in a near-physiological state allowing for extended ex-situ intervals with functional assessment of organ. Emerging evidence supports the safety and efficacy of the heart OCS use which may be suited to “extended criteria” recipients due to the increasing complexity of candidates including simultaneous heart kidney transplant (HKT). Avoidance of severe primary graft dysfunction (PGD) of heart is the key for successful HKT as failure of the initial step can be associated with poor kidney graft outcome or potentially result in deferral of kidney transplant. This study aims to present a single-center experience in utilizing OCS for brain death heart donors in simultaneous HKT.

Methods: We analyzed 8 consecutive combined heart-kidney transplants following brain death at our institution from May 2022 to January 2023 out of 63 heart transplants (HTs). Five patients who underwent HT with OCS were identified, and detailed data on their cases are reported. In our institute, kidney transplant was performed following HT with at least 4-6 hours of resuscitation in the intensive care unit.

Results: The mean age of recipients was 50 years, all of whom were male. Four of these patients had CKD, with two requiring renal replacement therapy prior to transplant. All patients were listed as status 2 priority, with four patients supported by the Impella 5.5 device prior to transplant. The waiting list duration varied from 8 to 83 days. Two patients initially had ECPella support (venoarterial extracorporeal membrane oxygenation (VA-ECMO) support and Impella 5.5) which was weaned to Impella 5.5 alone by the time of transplant.

The mean distance travelled with the utilization of OCS was 580 miles ranging from 177 miles to 1065 miles with a mean out-of-body time of 6.3 hours. The mean OCS time was 4.8 hours with mean ischemic time of 1.5 hours. Detailed individual patient data is shown in Table. There was 100% survival with no cases of PGD. There was no deferral of patient between heart and kidney transplant who was listed for combined HKT. There was also 100% freedom from dialysis on discharge.

Conclusion: The utilization of OCS demonstrates safe and promising outcomes in combined HKT. Our findings indicate that OCS effectively reduces ischemic time and supports the viability of donor hearts over extended distances. The absence of PGD and the ability to proceed to subsequent kidney transplant in all cases underline the potential of OCS in improving HKT outcomes warranting further investigation.

Table: Patients undergoing heart kidney transplant with OCS for donor heart

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Recipient age	57	59	37	44	56
Recipient sex	Male	Male	Male	Male	Male
Recipient BMI	27	25.5	25.5	29.5	33.6
Etiology of heart failure	Non-ischemic	Ischemic	Non-ischemic	Allograft dysfunction	Non-ischemic
Creatinine on admission	1.9	3.1	4.9	6.3	5.4
Pre-transplant dialysis	No	No	No	Yes	No
Pre-transplant MCS	IABP	Impella 5.5	VA ECMO Weaned to Impella 5.5	VA ECMO Weaned to Impella 5.5	Impella 5.5
Prior cardiac surgery	Yes	No	No	Yes	No
Blood group	B	A	B	O	O
UNOS listing status	2	2	2	2	2
Waitlist days	8	29	8	47	83
Donor age	27	30	28	37	43
Donor sex	Male	Female	Female	Male	Male
Cause of death	Anoxia	Stroke	Head trauma	Anoxia	Head trauma
OCS parameters					
Distance travelled	461	640	1065	177	560
OCS perfusion time	4.88	4.88	6.03	4.7	4.06
Total ischemic time	1.42	1.43	1.37	1.47	1.78
Total preservation time	6.3	6.3	7.4	5.72	5.84
Clinical outcomes					
In hospital survival	Yes	Yes	Yes	Yes	Yes
Severe PGD of heart	No	No	No	No	No
Donor kidney					
Kidney delayed graft function	Yes	No	No	No	No
Dialysis at discharge	No	No	No	No	No
Most recent follow-up (Days alive)	521	269	262	174	4

CARC23

Root of the Myth: Where Does the Idea of 4°C Ice Storage Come From and Why Does it Matter?

Ben Bulka, Lucas Churchill, Alana Brockman, Michael Tajima; *Paragonix Technologies, Acton, Massachusetts, United States*

Background: Throughout extensive peer-reviewed literature in high impact journals, even in the past-year, the temperature of organs stored on ice is described as 4°C. In this study, we seek to explain where this idea came from, why it does not represent the thermal environment of donor organs, and why this matters in modern organ preservation. We study the phase change of three common liquids and use these to understand the impacts of solution composition on thermal environments.

Methods: Three containers were filled with 3L of Tap Water, UW Preservation Solution, and 70% Isopropyl Alcohol (IPA) and equipped with temperature probes at the bottom of the containers. Containers were placed in a consumer freezer set to -20°C and monitored for temperature changes.

Results: The probe inserted into Tap Water (A) reports a decrease in temperature until 4°C where it plateaus for about an hour, after which (B) it resumes the decrease in temperature until reaching freezing at 2.5 hours. UW Solution exhibits (C) no plateau of temperature at 4°C and has a continuous decrease to below freezing temperatures with the bottom probe reaching -4°C before changing phases. IPA has a continuous decrease in temperature throughout the preservation period with no phase change.

Discussion: The probe of the Tap Water experiment demonstrates the effect of peak density of fresh water, which occurs at 4°C and causes the bottom of the container to stabilize at this temperature. This may be the potential basis of the concept of 4°C ice storage, that as long as the organ is submersed at the bottom of a container of liquid water, without direct contact to ice, it will be preserved at 4°C. There are several key flaws in this assumption. Most importantly, organs are not stored in Tap Water, and as shown in the UW experiment, solutes in water can drastically change the solution's thermal characteristics. This creates an environment where organ tissue can be in direct contact with liquid solution that is below zero despite the preservation solution not changing phase to a solid state. The UW performance is more consistent with the IPA experiment until the UW reaches solidification. This exemplifies the thermal dangers of surrounding an organ to direct contact with liquids at or below 0°C.

Conclusions: Temperature is increasingly being recognized as a critical element in hypothermic organ preservation. Publications describing temperature in organ preservation should be careful to report actual measured temperatures. This study demonstrates that common expectations around organ preservation may not be the reality of actual preservation environments.

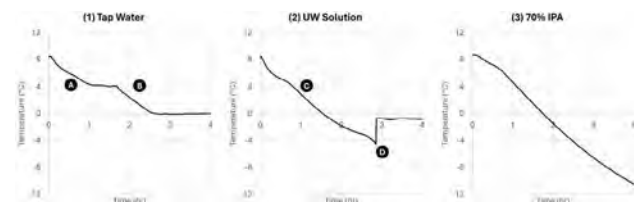


Figure 1. Measured temperatures at the bottom of containers of representative fluids placed into a freezer at -20°C. (A) Tap Water exhibits a plateau at 4°C based on the characteristic of peak density, which is the basis of the ice storage assumption (expectation). (C) Actual preservation solutions experience no such plateau and can reach (D) sub-zero temperatures (reality).

CARC24

Socioeconomic Disparities in Simultaneous Heart-Kidney Transplants: An Analysis of the UNOS Registry

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Background: Simultaneous heart-kidney transplantation (HKTx) represents guideline-directed treatment for heart failure with persistent irreversible renal dysfunction. However, persisting barriers hinder equitable access and influence post-transplant outcomes. We sought to determine socioeconomic disparities in post-transplant survival outcomes in patients receiving HKTx.

Methods: We examined the United Network for Organ Sharing (UNOS) registry to identify patients who underwent HKTx since its inception in 1988. We stratified race into White, Black, Hispanic, Other. We analyzed donor and recipient characteristics along with recipient survival outcomes. Three-year survival outcomes were expressed as Kaplan-Meier (KM) survival curves and time-dependent survival as Cox proportional hazard models.

Results: Of 3379 patients in the HKTx cohort, 1729 (51%) were White, 1123 (33%) were Black, and 326 (9.6%) were Hispanic. Cardiomyopathy was the most common primary diagnosis (n=1677/3395, 49%). Private insurance coverage was most common for White (n=945/1734, 49%) and Black patients (n=454/1123, 41%), while Medicare was most common for Hispanic patients (n=119/326, 37%). Race-adjusted KM survival analysis revealed no statistically significant differences between groups (Figure 1), but Hispanic patients had higher survival compared to non-Hispanic patients together (p=0.031). Hispanic patients also had greater survival compared to White patients, confirmed by Cox multivariate analysis (Figure 2)- hazard ratio (HR) for death (95% confidence interval) of 0.74(0.56,0.98, p=0.034). Notably, female Hispanic patients reported unfavorable post-transplant outcomes compared to Hispanic males (HR-2.30(1.19,4.47), p=0.014). Female donor hearts were associated with worse outcomes overall (HR-1.30(1.11,1.53), p=0.001), especially in White (HR-1.45(1.17,1.81), p<0.001) and Black patients (HR-1.38(1.02,1.87), p=0.038). While insurance did not correlate with survival, Medicare-sponsored White patients (HR, 1.25(1.01,1.54), p=0.043) and Medicaid-sponsored Hispanic patients (HR-2.35(1.01,5.44), p=0.047) showed increased risk of death. Among primary diagnoses, coronary artery disease had increased risk of death compared to cardiomyopathy (HR-1.18(1.01,1.38), p=0.039). Further, reduced survival was seen in Black patients listed with congenital heart disease (HR-8.45(1.96,36.4), p=0.004) and Hispanic patients with graft failure (HR-3.01(1.36,6.67), p=0.007).

Conclusion: Hispanic recipients experienced better three-year post-transplant outcomes after HKTx, with contrasting negative outcomes in females. Notably, female donor hearts appeared to confer poor survival outcomes in White and Black recipients. Finally, insurance disparities were identified in White and Hispanic patients. Further studies are warranted to assess these disparities, particularly focusing on barriers to healthcare access.

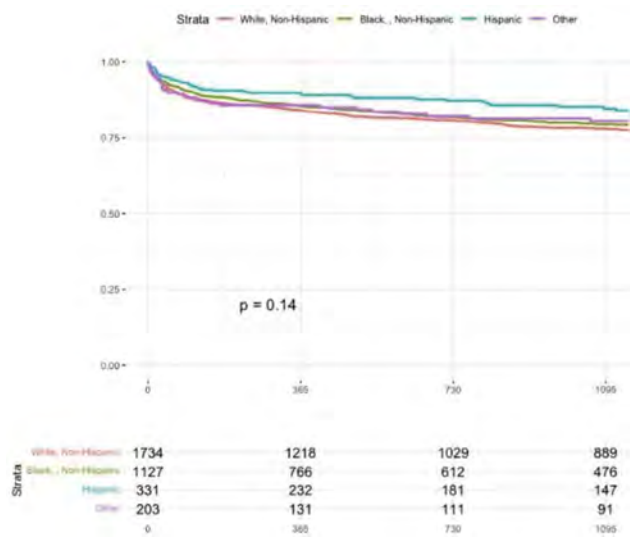


Figure 1. Race-Stratified Kaplan-Meier Survival Analysis

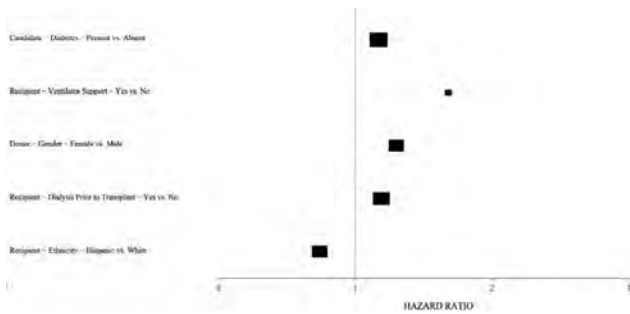


Figure 2. Forest plot showing Cox Multivariate Hazard Ratios

BIO1

A Single-Pass System to Characterize Flow-Induced Hemolysis: Effect of Blood Species and Hematocrit

Sailahari Ponnaluri, Moustafa Meki, Luke Herbertson, Qijin Lu, Brent Craven, Richard A. Malinauskas; *Division of Applied Mechanics, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, Food and Drug Administration, Silver Spring, Maryland, United States*

Exposure to high fluid stresses from blood contacting medical devices can lead to an elevated risk of hemolysis. To assess blood damage potential, pump developers perform *in vitro* hemolysis testing in accordance with the ASTM F1841 standard. However, options in test parameters such as species, anticoagulant, blood collection method (abattoir vs. venipuncture), and hematocrit (HCT) adjustment method can lead to variability in hemolysis results. Understanding how test parameters impact hemolysis will improve the blood damage assessment of new devices per ASTM F1841 and help to develop computational fluid dynamics (CFD) models to predict hemolysis. Here, a single-pass blood flow model with short exposure times was developed to characterize the impact of species and HCT on flow-induced hemolysis.

A pneumatically driven single-pass flow system provided a low-cost, repeatable method to inject small blood volumes through nozzles at high pressures and different flow rates (Fig. 1A). Plastic nozzle models with converging tips (apex inner diameter of 410 µm) were assembled in-house. Blood from pigs, cows, sheep, and humans (n=5-6 for each species) with Anticoagulant Citrate Dextrose Solution A was shipped (animal blood) or stored overnight (human blood), filtered, and adjusted to 35% HCT by hemoconcentration via centrifugation or hemodilution with phosphate buffered saline. On each test day, room temperature blood was injected at different flow rates. Additionally, pig blood was adjusted to 25%, 35%, and 45% HCT using plasma (n=4). Static background blood samples were used to correct for baseline hemolysis levels. Blood samples were centrifuged twice to isolate and quantify the plasma free hemoglobin (pfHb) concentration based on optical absorbance using the Cripps method.

Using a single blood source, the reproducibility of the system (testing a single tip by alternating low and high flow rates for 6 cycles) and repeatability (testing five separate tips) was acceptable with a coefficient of variation of 1% for flow rate and less than 6% for hemolysis. For all species, although the average viscosity of 35% HCT blood ranged from 3.6 to 4.5 cP, the hydrodynamic pressure-flow curves were similar. PfHb levels for all species increased with flow rate, being lowest for sheep blood and markedly greater for human, potentially due to their larger red blood cell size (Fig. 1B). Increasing HCT resulted in more hemolysis that did not scale linearly (Fig. 1C). To extend the use of the single-pass model for providing benchmark hemolysis data to validate CFD based hemolysis models, the flow environment will be characterized using particle image velocimetry. Moreover, to align with the testing of medical devices per the ASTM F1841 standard, the effects of blood properties (e.g., species, anticoagulation) will be evaluated using this benchmark nozzle flow model in a recirculating flow loop.

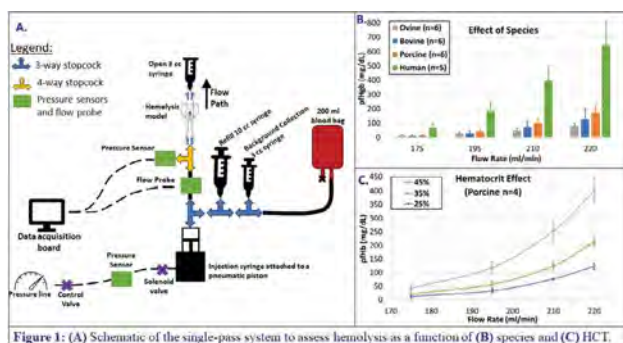


Figure 1: (A) Schematic of the single-pass system to assess hemolysis as a function of (B) species and (C) HCT.

BIO2

Bivalirudin as a Direct Thrombin Inhibitor in a Polymer Surface Coating

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Background: Direct Thrombin Inhibitors (DTI) such as Argatroban (Arg) or Bivalirudin (Bival) are frequently used systemically in extracorporeal life support (ECLS) as substitutes for heparin anticoagulation. Our laboratory has demonstrated the successful use of Arg in surfaces of extracorporeal circuits (ECCs). These circuits are designed to avoid the use of systemic anticoagulation and mitigate clotting and excess bleeding during ECLS. This study evaluates the viability of coating surfaces with Bival as an alternative to Arg by analyzing its thrombin inhibition capacity (TIC) *in vitro*.

Methods: An isocyanate linker was used to immobilize Bival to the polymer CarboSil® and after precipitating the product with hexane and washing away the free linker, the substance was re-dissolved in tetrahydrofuran (THF). The substance was then analyzed by Fourier-transform infrared spectroscopy (FTIR) to ensure proper bonding of Bival to CarboSil® via the isocyanate functional group. DTI functionality of the Bival/CarboSil® polymer was tested *in vitro* using an antithrombin chromogenic assay to measure product cleavage by thrombin into remaining peptides and free p-nitroanilide (PNA), as the chromophore. The absorbance difference was measured by a microplate reader at 405 nm and was used to evaluate its efficacy.

Results: FTIR data showed a decrease in the peak size (at 2250 cm⁻¹) for the isocyanate group, demonstrating Bival bound to the linker and polymer. The antithrombin assay showed that the TIC for immobilized Bival was 1.0 µM/L which is ca. 2.5 times higher than previously reported Arg (TIC= 0.4 µM/L). These concentrations were evaluated using a standard curve with a range from 0 to 1 µM, where 1 µM means the highest thrombin inhibition.

Conclusion: We report the first use of a novel surface-bound coating with Bivalirudin and demonstrate its efficacy and feasibility for potential prevention of thrombus formation on extracorporeal polymer surfaces. Future docking and structure-activity relationship (SAR) studies may be performed to learn about the molecule's unique binding and biological capabilities. Our future goal is to expand our research to assess the viability of the Bival coating in an *in vivo* model.

BIO3

In vitro Evaluation of Turbulence-induced Blood Trauma in a Single-Pass Flow System

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Background: The impact of non-physiological turbulence generated from ventricular assist devices (VADs) is poorly understood and often ignored in whole blood trauma characterization. Prior *in vitro* experiments employing a recirculating flow loop with a blood pump, reservoir, and capillary throttle, shown in Figure 1a, have shown greater mechanical hemolysis in turbulence than laminar flow at equivalent wall shear stress. However, such recirculating loops suffer from significant artifact due to blood damage introduced by the pump, obscuring the independent effect of turbulence in the capillary.

Methods: A single-pass flow system was configured, consisting of blood reservoir bag, a collection bag, and an interposed 1 mm inner diameter, 70 mm length glass capillary tube, as shown in Figure 1b. 100 mL blood samples were throttled through the capillary tube by pressurizing the upstream reservoir to produce wall shear stresses of 100, 250, and 400 Pa. To compare laminar and turbulent flow at the same shear stress, the viscosity was adjusted with saline or dextrose solution (Dextran-40). Multiple passes were performed to achieve an equal exposure time of 50 seconds for both laminar and turbulent conditions. Resuspended bovine cells were used for evaluating RBC damage, while whole ovine blood was used for platelet analysis. The calculated Reynolds number was computed to characterize the flow regime in each trial. Laminar flow trials were in range of 900 - 1400 Re while transitional/turbulent flow trials were defined as 5,000 - 6,000 Re range. Mechanical hemolysis was evaluated by measuring the change in plasma free hemoglobin. Flow cytometry was used to measure change in platelet activation through P-selectin (CD62p) expression.

Results: Previous testing with a traditional VAD-based flow loop showed numerically greater hemolysis and platelet activation, but significance was limited by data variance. The single-pass system reported here, which eliminated the artifactual damage produced by the loop, provided statistically significant greater damage to RBCs by turbulence compared to laminar conditions, although platelet trauma was not statistically significant between the two Reynolds numbers.

Conclusion: This study is the first of its kind to isolate effects of turbulent flow on whole blood damage without artifactual damage of a recirculating loop.

This study is dedicated to the memory of Brian Frankowski, an integral member of the Pittsburgh artificial organ community, whose mentorship, knowledge, and willingness to help everyone have helped many medical device research studies achieve success.

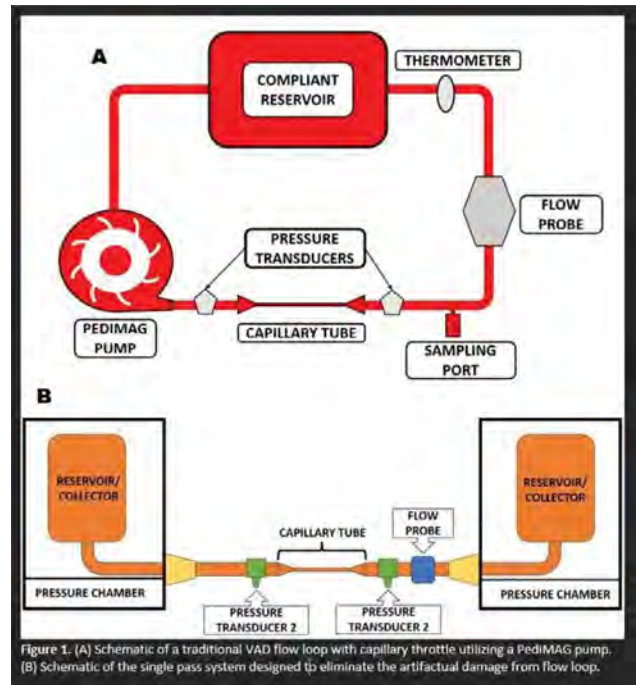


Figure 1. (A) Schematic of a traditional VAD flow loop with capillary throttle utilizing a Pedimag pump. (B) Schematic of the single pass system designed to eliminate the artifactual damage from flow loop.

BIO4

The Impact of Yield-Stress on Thrombus Formation Susceptibility in Venous Valves: A Comparative Study Using Rheological Models

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The effect of blood rheology on flow patterns in coronary arteries, with particular emphasis on wall shear stress and its effect on stenosis, has been extensively studied. Much less effort has been focused on the influence of blood rheology on the susceptibility to thrombus formation in a venous valve pocket. This work addresses the question of the specific effect of the presence or absence of blood yield stress on the flow patterns within and around venous valves by using two rheological models previously applied to blood flow, one with and one without yield stress.

The parameters in the models were determined by fitting each of them to a set of recently published blood rheological data, carried out at shear rates between 0.05 and 700 s⁻¹. The models are then applied to simulations of flow through a realistic, three-dimensional model of a venous valve, to assess the relative likelihood of thrombogenesis under various scenarios. Flow features compared are the relative size of the stagnant zone in the venous valve pocket and the strength of the jet emerging from the valve at the leaflet edges, under normal flow, and the strength of the recirculation zone flushing out the venous valve pocket for a closing valve. Our findings have significant implications for understanding thrombogenesis in venous systems and could inform new strategies for clot prevention.

BIO5

A Study of Centrifugal Pumps and their Propensity for Hemolysis

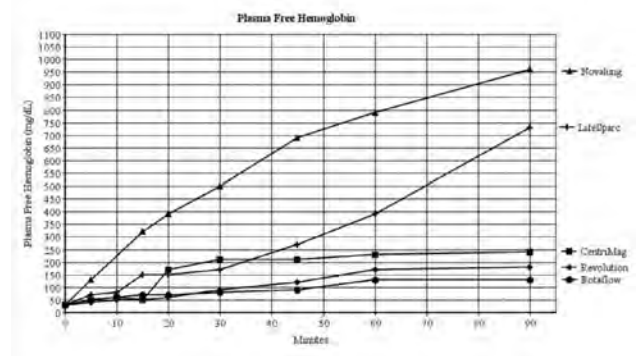
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Background: Hemolysis during ECMO support is attributable to numerous factors including components and design of the circuit, characteristics of the pump and oxygenator, level of flow and areas of turbulence, as well as patient factors including sepsis and hematologic disorders. Thus, pinpointing the definitive cause of observed hemolysis in a specific patient or groups of patients can be difficult and potentially inaccurate. Using identical modified mini-circuits and blood from a single source, with the only variable being the device, we compared 5 commonly used centrifugal pumps to differentiate their propensity to cause hemolysis at a standardized flow rate.

Methods: Five identical setups were constructed using 4 foot loops of 3/16" tubing, tapered with 4" of 1/4" tubing, and 4" of 3/8" tubing to allow connection to the pump heads. Access for blood sampling was through a side port of the 1/4" to 3/8" connector on each side. Approximately 625cc of whole blood was obtained from a single donor, heparinized, and mixed with normal saline in a priming bag to provide sufficient volume for the 5 circuits as well as replacement for the study samples to keep the circuit volumes stable, and to reduce the hemoglobin level to around 11g/dL. The 5 pumps were started simultaneously and the RPM increased to achieve a flow of 3.6-3.8 L/m as measured by Transonic Flowmeter. A baseline sample was taken from the initial prime bag, and then samples obtained from each circuit at 5, 10, 15, 20, 30, 45, 60 and 90 minutes of circulation. Samples were measured for Hemoglobin and Hematocrit, LDH, Plasma Free Hemoglobin and Hemolysis Index. The following RPMs were required to achieve the desired flows in the 5 devices: CentriMag 4400, LifeSparc 6700, NovaLung 8700, Rotaflow 4020, Revolution 2575.

Results: Over the 90 minute study, all circuits show increasing hemolysis at variable rates, as demonstrated by a rise in Plasma Free Hemoglobin, LDH and Hemolysis Index. The higher levels of hemolysis were associated with the devices with smaller volume cones which require higher RPMs, with similar graph patterns with all three tests (PF HGB, LDH, Hemolysis Index). There was no measurable decrease in Hemoglobin or Hematocrit over the 90 minutes in any of the five circuits.

Conclusion: In a direct comparison using identical circumstances including blood composition and character, in an intentionally exaggerated model of a turbulent mini-circuit design to stimulate hemolysis, the propensity for individual centrifugal pumps to cause hemolysis paralleled the level of RPMs required to produce a standard flow rate. This demonstrates a clear relationship of risk of hemolysis with higher centrifugal pump RPM, making it more of a concern in the devices that require higher RPM to function. This information can be of value in selecting the appropriate device for a specific patient population, along with factors such as length of runs, support required, mobility, and cost.



PLASMA FREE HEMOGLOBIN LEVELS

BIO6

Computational Modeling and experimental characterization of Platelet Adhesion Dynamics on Collagen- and VWF-Coated Surfaces

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Platelet adhesion and aggregation are crucial for primary hemostasis to form a clot that rapidly stops the initial bleeding. Platelets bind to the exposed collagen and Von Willebrand factor (VWF) to the injury site via dynamic interactions with platelet receptors, initiating the initial thrombus formation. The initial thrombi have a dense and stable core but a highly dynamic and unstable periphery. The receptor-ligand binding characteristics can influence platelet adhesion and detachment under different blood flow conditions. In this study, we investigated the dynamic growth of platelet adhesion/aggregation on collagen- or VWF-coated surfaces in a microchannel in vitro. In parallel, a stochastic dissipative particle dynamics (DPD) model incorporating the binding rate of platelet adhesion and detachment using Bell's law was developed to describe thrombosis formation concerning different pairs of platelet receptor ligands. Platelets and collagen- or VWF-coated surface and wall surfaces are considered spherical molecules with different sizes. The predicted platelet adhesion by the stochastic force model replicated the experimental characteristic patterns of platelet adhesion to the collagen- and VWF-coated surfaces. Further quantification of the growth rate of the thrombus area showed good agreement with the experimental results at different shear rates. The quantitative formulas derived in this model could be further adapted to describe hemostatic disorders resulting from alterations in platelet function, e.g., shear-induced platelet activation and receptor shedding.

BIO7

Quantitative Enzymatic-Mechanistic Differentiation of Multimeric Degradation of von Willebrand Factor in Turbulent Flows

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Background: Continuous flow left ventricular assist devices (cf-LVADs) have been known to cause degradation of high molecular weight multimer (HMWM) of von Willebrand factor (vWF), eventually, leading to acquired von Willebrand syndrome (AvWS). It is understood that supraphysiologic shear stress created by highly irregular and disorganized blood flow in cf-LVADs leads to structural changes of vWF multimers, thus, exposing the A2 domain cleavage site for ADAMTS13 that cleaves HMWM of vWF. However, it is still unclear whether the cleavage mechanisms are purely mechanistic, purely enzymatic, or a combination of the two. This study is to quantify the contributions of each degradation mechanism at clinically relevant flows and exposure times observed in most cf-LVADs.

Methods: Diluted ovine blood with an adjusted hematocrit of 25%, a viscosity of 3.5 cP, and a density of 1,030 kg/m³ flowed through a custom high shear rotary device (Fig. 1) to obtain the combined degradation mechanisms (i.e., mechanistic and enzymatic). The flow rate was set at 1.75 ml/sec, 0.76 ml/sec, or 0.38 ml/sec, resulting in an exposure time of 22 ms, 50 ms, or 100 ms, respectively. The dynamic flow condition was controlled by the speed of the rotor, ω , and characterized by the energy dissipation rate per unit mass, ϵ . The ω of 10k, 15k, and 20k RPM was applied, and the corresponding ϵ along with the total shear stress, τ (i.e., laminar + turbulence) were estimated by running a series of large eddy simulations (LES). The entire tests were repeated after adding ethylenediaminetetraacetic acid (EDTA) with a concentration of 10 mM to the blood to inhibit ADAMTS13, a vWF cleaving protease, thus, excluding the effect of the enzymatic contribution from the total loss of HMWM of vWF. After each run, a 0.5 ml sample solution was collected for multimer analysis.

Results: At 10k and 15k RPM corresponding to ϵ of $\sim 6,000 \text{ m}^2/\text{s}^3$ ($\tau \sim 200 \text{ Pa}$) and $\sim 14,000 \text{ m}^2/\text{s}^3$ ($\tau \sim 300 \text{ Pa}$), respectively, mechanical contribution to the total degradation seemed negligible (Fig. 2A, 2B). However, at 20k RPM corresponding to ϵ of $\sim 24,000 \text{ m}^2/\text{s}^3$ ($\tau \sim 400 \text{ Pa}$) (Fig. 2C), we began to see the mechanistic contribution to the total degradation at around 20 - 30 % while the enzymatic contribution appeared to be still dominant.

Conclusion: To the best of our knowledge, this is the first study that quantifies the degradation mechanism in the loss of HMWM of vWF in terms of mechanistic and enzymatic contributions at clinically relevant blood flows and shear exposure times observed in most cf-LVADs. The outcome of the study provides pivotal insights into the underlying pathophysiology of AvWS in the use of cf-LVADs, guides to device optimization for next-generation blood pumps, and potential therapeutic targets for patients with cf-LVADs experiencing AvWS.

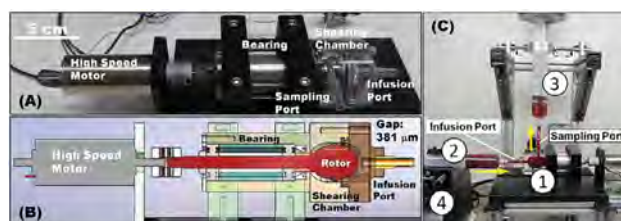


Fig.1. (A) custom high shear rotary device (Ultimate Speed Degradator, USD), (B) cross-sectional view of USD, (C) experimental Setup; 1. USD, 2. 60-ml syringe containing the pre-shear ovine blood, 3. 60-ml syringe to collect the post-shear ovine blood, 4. Syringe pump.

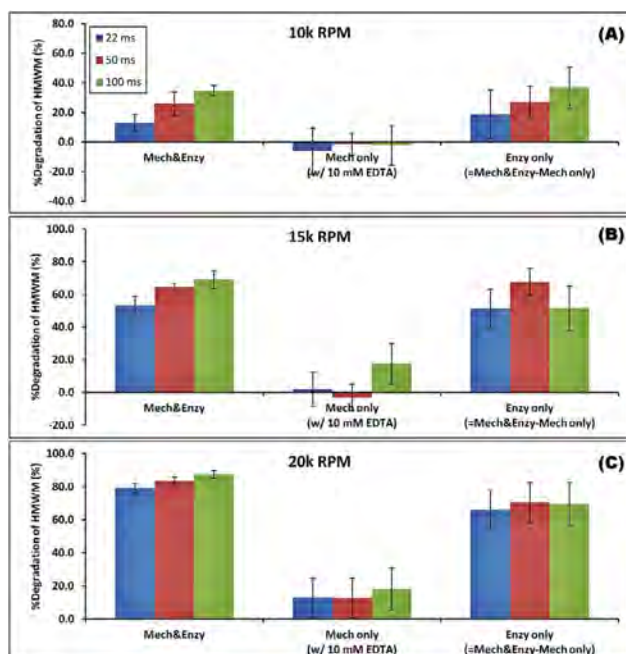


Fig.2. The combined (Mech&Enzy), mechanistic (Mech only, w/ 10 mM EDTA), and enzymatic (Enzy only = Mech&Enzy – Mech only) contributions on degradation of vWF at (A) 10k RPM ($\epsilon \sim 6,000 \text{ m}^2/\text{s}^3$, $\tau \sim 200 \text{ Pa}$), (B) 15k RPM ($\epsilon \sim 14,000 \text{ m}^2/\text{s}^3$, $\tau \sim 300 \text{ Pa}$), and 20 k RPM ($\epsilon \sim 24,000 \text{ m}^2/\text{s}^3$, $\tau \sim 400 \text{ Pa}$).

BIO8

Effect of Increased Pulse Frequency on Shear-Induced Extensional Behavior of Von Willebrand Factor (VWF)

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Background: Patients with continuous flow ventricular assist devices (CF-VADs) face a high risk of non-surgical bleeding, likely due to the loss of pulsatility post-CF-VAD placement. To counter the adverse effects of diminished pulsatility, modulating CF-VAD flow through rapid pump speed changes has been suggested as a strategy to generate “artificial pulsatility”. However, the impact of frequency of artificial pulsatility on VWF unravelling behavior remains largely unexplored and could potentially have a critical impact on the prevention of non-surgical bleeding.

Methods: VWF molecules were immobilized on the surface of microfluidic devices and exposed to pulsatile flows with waveforms of different pulse frequencies (10, 40, and 60 pulse/min), along with continuous flow (100 $\mu\text{L}/\text{min}$), mimicking the shear flow environments with and without CF-VAD support. Images of elongation of VWF molecules ($n=45$) were observed using total internal reflection fluorescence (TIRF) microscopy. The average VWF length (calculated using a time-weighted average), was measured for molecules under each pulse frequency and subsequently normalized by the average flow rate for each condition. One way ANOVA was performed to compare the average VWF lengths.

Results and Discussion: Our findings indicate a noticeable reduction in the length of VWF molecules under pulsatile shear flow compared to continuous shear flow across all pulse frequency conditions. Moreover, the average VWF lengths at each pulse frequency demonstrated a clear trend, with higher pulse frequencies associated with shorter average extensions. This observed significant reduction in VWF extension under pulsatile flow, coupled with the conclusion that molecules exhibit shorter extensions at higher pulse frequencies compared to lower frequencies ($p<0.001$), offers valuable insights for designing flow modulation patterns in VADs to minimize VWF unravelling. As VWF unraveling has been shown to expose ADAMTS13 cleavage sites and increase enzymatic degradation of VWF into low MW multimers that are compromised in their ability to facilitate coagulation, this study provides important information that can be used to identify optimal frequencies for flow modulation protocols to prevent excessive degradation of VWF.

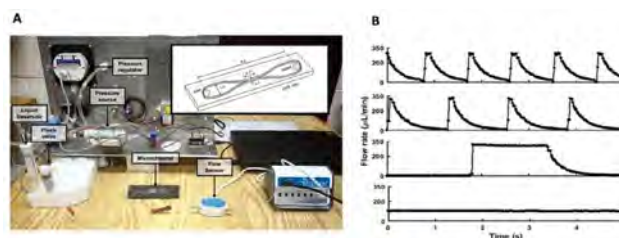


Figure 1. (A) Pulsatile pump setup and microfluidic channel dimensions (inset). (B) Pulse frequencies waveforms (10, 40, 60 pulse/min) and continuous flow waveform (100 $\mu\text{L}/\text{min}$).

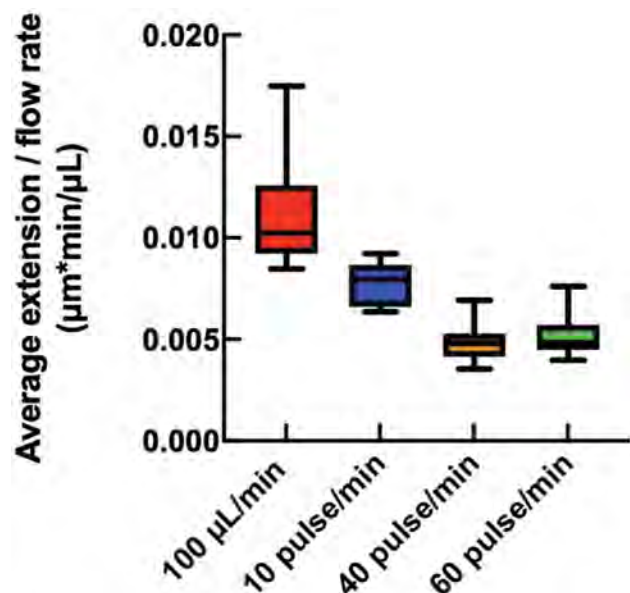


Figure 2. Box and whisker plots of averaged extensional length normalized by the mean flow rate.

BIO9

In Vitro Human Blood Damage Profile of the Syncardia TAH and the Realheart TAH in a Full Body Circulation Test Rig

Shaikh Faisal Zaman¹, Kerstin Jönsson Videsäter², Simon L. Videsäter¹, Tatiana Khudur², Thomas Finocchiaro¹, Ina Laura Perkins¹; ¹Research and Development, Scandinavian Real Heart, Västerås, Sweden, ²Karolinska University Hospital, Stockholm, Sweden

Background: Syncardia Total Artificial Heart (TAH) is approved for bridge to transplantation by the FDA and has been implanted in more than 2000 patients to date. Hemolysis has been reported post implantation in these patients but there is no published in vitro test data which encompasses hemolysis and/or hematology.

Realheart TAH is a novel positive displacement TAH which displaces fluid based on the translation of its atrioventricular (AV) plane. It is currently in the pre-clinical stage.

The aim of this study was to evaluate the blood damage profile of the Syncardia TAH in a full body circulation test rig in vitro using the Realheart TAH as a comparison, while maintaining clinically relevant preload and afterload with human blood.

Methods: In vitro hemolysis testing was performed for full body circulation with the Syncardia and Realheart TAH. Iterative testing was performed compiling to the ASTM standards, F1830-97 and F1841-97 (2017) with pooled, cross-matched human whole blood with citrate phosphate dextrose (CPD) as the anticoagulant. Dilution with PBS solution was done to attain a hematocrit (Hct) of 30 ± 2%. A clinically relevant afterload and preload of 85 ± 3 and 7 ± 3 mmHg respectively, for the systemic circulation, while 40 ± 3 and 7 ± 3 mmHg for the pulmonary circulation were maintained.

Plasma free hemoglobin (pfHb) was measured using the Harbore spectrophotometric assay at wavelengths 380, 415 and 450 nm. Hematology was analyzed from whole blood samples using Swelab Alfa Plus (Boule). Milligram normalized index of hemolysis (mgNIH) and modified index of hemolysis (MIH) were calculated. Kruskal-Wallis H test was performed for statistical analysis.

Results: The mean flow and pressure head (left/right) for the Syncardia TAH (n=5) were 6.2±0.2 L/min and 77.3±1/ 33.0±1.6 mmHg while for the Realheart TAH (n=5) were 6.2±0.2 L/min and 78.1±1/ 33.4±1.2 mmHg. The Syncardia TAH showed 6 times higher mgNIH compared to the Realheart TAH (p=0.009).

A significant (abnormal) increase in platelet count was observed over time for the Syncardia TAH (p=0.009, 360 minutes). There was a significant decrease in granulocytes (p=0.01, 360 minutes) for both the Syncardia and Realheart TAH, with a concomitant significant increase in monocytes (p=0.007, 360 minutes) when comparing with the negative control. This is best explained by a change in granulocyte morphology causing a shift of the cell from the granulocyte detection gate to the monocyte gate.

Conclusions: In vitro human blood damage profile, including hemolysis and hematology, of the Syncardia TAH and Realheart TAH were evaluated in a full body circulation test rig while maintaining clinically relevant parameters. The Syncardia TAH showed a significant increase in hemolysis compared to the Realheart TAH and an abnormal increase (false positive) in platelet count which could be fragmented red blood cells due to high hemolysis.

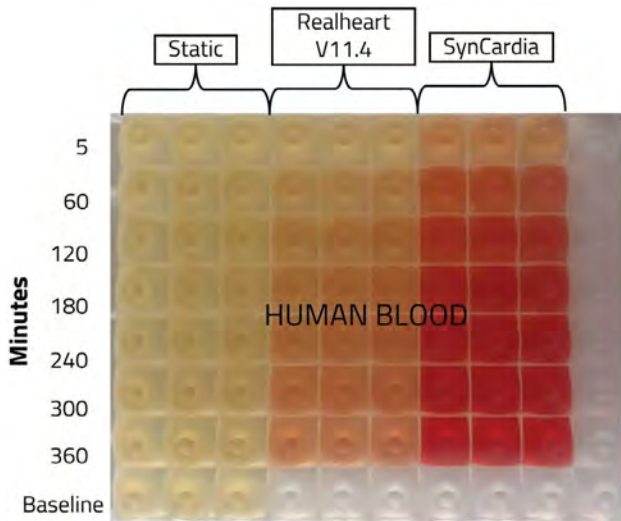
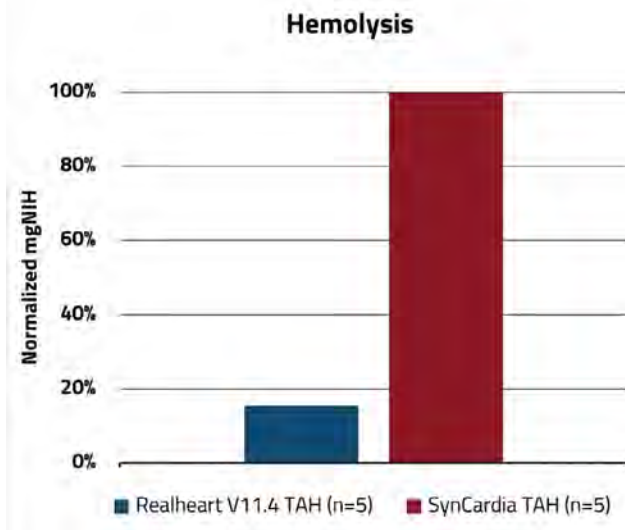


Image of the deep well plate at the end of a hemolysis test. The rows depict sampling timepoints (in minutes) while the columns correspond to the negative control, Realheart TAH and SynCardia TAH, respectively, in triplicates.



Relative mgNIH (n=5) of the Realheart TAH compared to the SynCardia TAH with pooled, cross-matched human whole blood.

BIO10

A Less-Invasive Left Atrial Assist Device Concept for Diastolic Heart Failure: Results of *In Vitro* Assessments

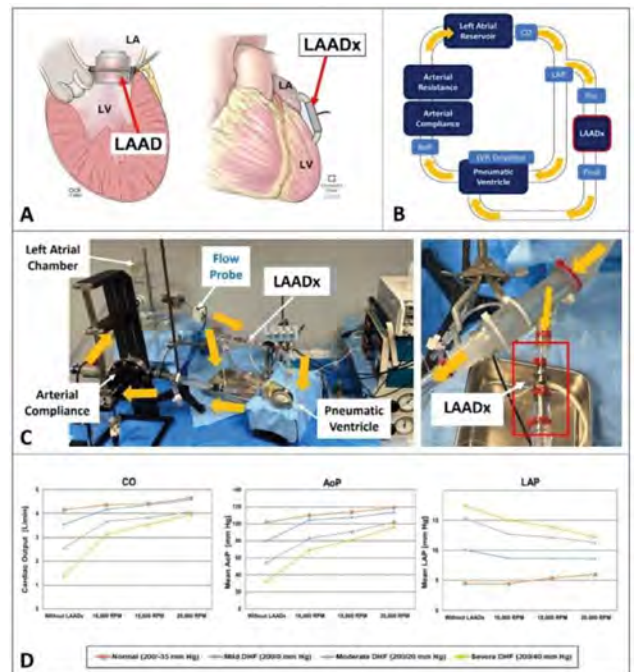
Chihiro Miyagi, Taiyo Kuroda, Barry D. Kuban, Christine R. Flick, Anthony Polakowski, Jamshid H. Karimov, Kiyotaka Fukamachi; *Biomedical Engineering, Cleveland Clinic Lerner Research Institute, Beachwood, Ohio, United States*

Background: Left atrial assist device (LAAD) is a blood pump that is implantable at the mitral annulus and intended for treatment of diastolic heart failure (DHF). We are developing a less-invasive version of LAAD, termed LAADx, which is placed outside of the heart as a parallel left pump circuit (Fig. 1A). The results of an *in vitro* assessment to validate the LAADx concept with/without simulated DHF filling restrictions is subsequently reported.

Methods: A mixed-flow pump was used as a working LAADx prototype, and its performance was evaluated under three predetermined, different speeds (16,000, 18,000, and 20,000 rpm) using an *in vitro* mock circulatory loop (Fig. 1B and 1C). The pneumatic ventricle achieved a normal heart condition with a driving pressure of 200/-35 mm Hg (systole/diastole). Three DHF conditions were induced by adjusting the diastolic drive pressure to 0 mm Hg (mild DHF), 20 mm Hg (moderate DHF), and 40 mm Hg (severe DHF); and the hemodynamics with/without the LAADx were recorded.

Results: Without the LAADx, cardiac output (CO) decreased from 4.2 to 1.4 L/min under normal heart to severe DHF settings. With LAAD support, CO recovered to 3.9 L/min even under severe DHF condition. Similarly, the decrease in aortic pressure and increase in left atrial pressure under no-pump/DHF conditions were mitigated by support of the LAADx (Fig. 1D).

Conclusion: In the *in vitro* mock loop simulation, the LAADx concept successfully demonstrated the intended hemodynamic effects with simulated DHF conditions.



BIO11

Alternative anticoagulant strategy to improve the ASTM F2888-19 Standard for Platelet and Leukocyte Count Assay

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Purpose: This study aimed to address two limitations of the ASTM F2888-19 standard for Platelet and Leukocyte Count Assay: low test sensitivity for leukocyte count and a high test sample surface area to blood ratio (12 cm²/ml) requirement for the test.

Methods: Four commonly used medical device materials: polytetrafluoroethylene (PTFE), high-density polypropylene (HDPE), 316L stainless steel (SS), and silicone (Si), and three thrombogenic materials: Buna-N rubber (Buna), latex, and glass beads (glass) were investigated. Fresh human blood from healthy adult donors (N = 6) was used within 2 hours of blood draw. For each test, the same donor's blood was drawn into two different anticoagulants: 3.2% sodium (Na) citrate and anticoagulant citrate dextrose solution A (ACDA). The blood was recalcified and heparinized immediately before starting the test, and then incubated with the test materials at a 6 or 12 cm²/ml surface area to blood volume ratio (Fig. 1A-B). The samples were incubated for 1 hour at 37 ± 2°C in a shaking water bath at a rotational speed of 60 rpm. Following the incubation, Ethylenediaminetetraacetic acid Tripotassium was added to the blood samples at a final concentration of 5 mM to inhibit clotting reactions. Finally, the blood samples were filtered through a polypropylene mesh (~104 µm) into a new tube and kept on ice until a complete blood count measurement was taken using a hematology analyzer.

Results: Both Na-citrated and ACDA-anticoagulated blood were able to differentiate thrombogenic materials (Buna, glass, and latex) from the other commonly used biomaterials (PTFE, HDPE, Si, and SS) based on platelet count (Fig. 1C). However, the magnitude of platelet count change between the thrombogenic materials and the other biomaterials was much larger for the ACDA blood (6 cm²/ml test sample surface area to blood ratio) than that for the Na-citrated blood (12 cm²/ml ratio). The test sensitivity was dependent on the heparin concentration level used in the ACDA blood and was optimized at 1 U/mL heparin. Moreover, the use of ACDA blood, as opposed to citrated blood, allowed the assay to distinguish between the thrombogenic materials and commonly used biomaterials based on leukocyte count (Fig. 1D).

Summary: Using the alternative ACDA-based anticoagulation strategy significantly increased the sensitivity of the ASTM F2888-19 method in differentiating the thrombogenicity of materials based on both platelet and leukocyte counts. This new anticoagulation also enables the test to be performed using a test sample surface area to blood ratio of 6 cm²/ml, which is half of the required ratio in the current ASTM F2888-19 standard (12 cm²/ml). This will also reduce the likelihood of unintended exposure of the test blood to the cut or sharp edges and non-blood-contacting portions of the test materials, which may produce inconsistent results. These findings will support the use of ACDA anticoagulation in a future revision of the ASTM F2888 standard.

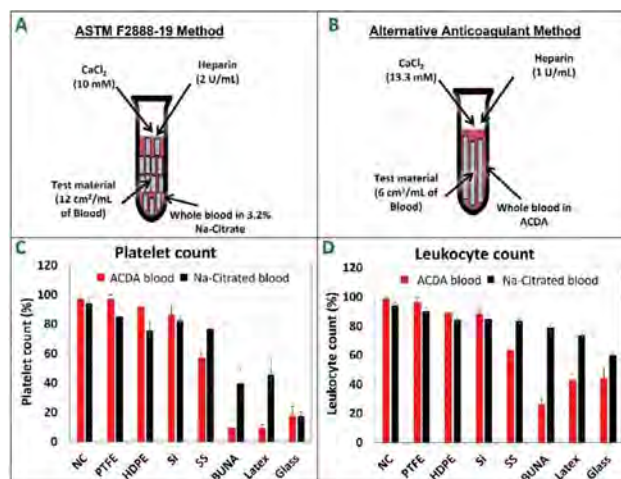


Figure 1. Experimental setup of (A) ASTM F2888-19 method and (B) proposed alternative anticoagulant method showing the test material segments were incubated in recalcified and heparinized whole blood for 1 hr at 37°C. For negative control (NC): Test was run without any test material. (C) Platelet count and (D) Leukocyte count in blood sample after incubating different test materials following ASTM F2888-19 method and Alternative anticoagulant method. % blood cell count for each test sample was calculated by change in blood cell count before and after 1 hr of incubation. Data are shown as mean ± SE, N = 6.

BIO12

Adhesion Dynamic Behavior of Shear-Injured Platelets by Circulatory Assist Device

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Background: Platelet adhesion is a crucial step in the initiation of physiological hemostasis. Mechanical shear stress in blood pumps used in left ventricular assist devices (LVADs) and extracorporeal membrane oxygenation (ECMO) systems can induce platelet activation and receptor shedding, potentially altering platelet adhesion. This study aims to investigate platelet adhesion behavior in pump-assisted circulatory support systems.

Methods: Fresh, healthy human blood was circulated in in-vitro flow loops assisted by a clinical centrifugal pump at a flow rate of 4.5 L/min under three different pressure heads (75, 150 and 350 mmHg) for 4 hours. Blood samples were collected at baseline and after 4 hours of circulation to perfuse a microchannel for real-time dynamic observation and quantification of platelet adhesion to collagen and von Willebrand factor (VWF)-coated surfaces using fluorescence microscopy. Platelet characteristics, such as platelet activation (PAC-1+), platelet receptors (GPIIb/IIIa, GPIb α and GPIIb) shedding, were also analyzed by flow cytometry.

Results: Platelets rapidly accumulated on the collagen-coated surface and formed stable, clumpy clusters that increased in size with perfusion time. The device-injured platelets resulted in smaller and thinner clumpy clusters after the 4-hour circulation. Adhesion of platelets to VWF occurred predominantly as individual cells, with some showing unstable translocation on the surface. More adherent platelets became unstable and translocated at an increased rate after the 4-hour circulation. A higher pressure head in the pump resulted in a more severe impairment of this platelet adhesion, and induced earlier platelet activation, receptor shedding and VWF degradation.

Conclusions: This study demonstrated a direct, dynamic observation of shear-injured platelet adhesion in vitro. Platelet adhesion function was altered to varying degrees by pump operation under different conditions. Understanding the device-induced change in platelet adhesion may help in the future development of improved circulatory support systems.

BIO13

Enhancing the Hemocompatibility of 3D-Printable Silicone Elastomers for Artificial Lung Applications

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Background: Current clinical hollow fiber oxygenators are prone to clotting, necessitating the use of systemic anticoagulation and thus increasing the risk of bleeding events. We seek to address these limitations by creating hemocompatible and biomimetic 3D printed artificial lungs. In this study, we investigate the nonthrombogenic effects of imbuing our polydimethylsiloxane (PDMS) based 3D-printable resin with hydrophilic molecules with the goal of reducing the body's natural coagulation response to foreign materials, coming closer to mimicking the native *in vivo* blood interface.

Methods: Our high-resolution PDMS resin for stereolithography was modified in three different ways by: 1) adding 1% 2-Methacryloyloxyethyl phosphorylcholine (MPC) to the base resin; 2) adding 1.8% Poly(ethylene glycol) methacrylate (PEGMA) to the base resin; or 3) infusing the neat PDMS devices with 2% dimethylsiloxane-[60-70% ethylene oxide] (PEG-PDMS) in ethanol post-printing. Biomimetic microfluidic capillary devices designed in SOLIDWORKS (Fig. 1) were printed on an Asiga MAX X27 UV printer, cleared of uncured resin, then tested for coagulation with freshly-drawn ovine whole blood (activated clotting time of 200-250 seconds) treated with fluorescent lipophilic carbocyanine cell membrane stain DiI C12(3) (DiI). Devices ($n \geq 12$ per group) were exposed to blood for 10 minutes at 0.8 mL/min (shear of 0.771 Pa), flushed with Phosphate-buffered saline, fixed with 2% Paraformaldehyde, then evaluated for clotting via fluorescent confocal microscopy (Leica Stellaris 5) and clotting area analyses. Statistical significance between groups was determined via a single factor Anova and one-sided unequal t-test.

Results: Clotting area analysis determined a 42.6%, 58.3%, and 65.2% decrease between negative control resin (FTD NanoClear) and 1% MPC, 1.8% PEGMA, and 2% PEG-PDMS infusion resins respectively and a 11.4%, 49.1%, and 57.5% decrease relative to the unmodified PDMS base resin. Cell deposition quantified by fluorescent intensity showed a 54.2%, 69.2%, and 88.3% decrease compared to FTD NanoClear and a 40.1%, 59.7%, and 84.7% decrease compared to the unmodified PDMS base resin for the 1% MPC resin, 1.8% PEGMA resin, and 2% PEG-PDMS infusion resin respectively. All results were statistically significant with the 2% PEG-PDMS Infusion devices performing the best by both metrics (Fig. 3).

Conclusion: The pre- or post-printing addition of hydrophilic molecules to our PDMS 3D printing resin significantly reduces clotting in microfluidic artificial vasculatures.

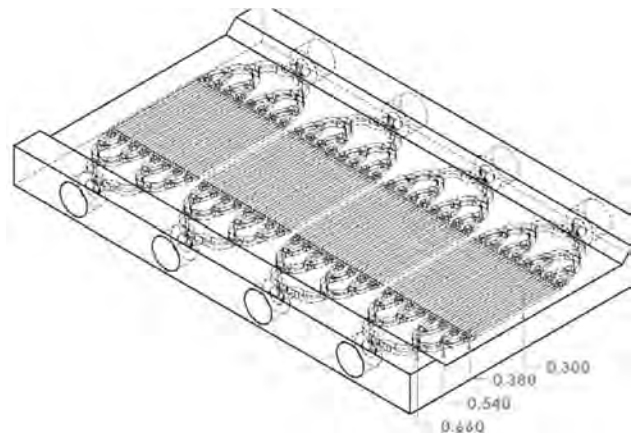


Figure 1. CAD engineering drawings of device capillary network showing relevant capillary dimensions and cross sectional distribution. All dimensions are in mm.

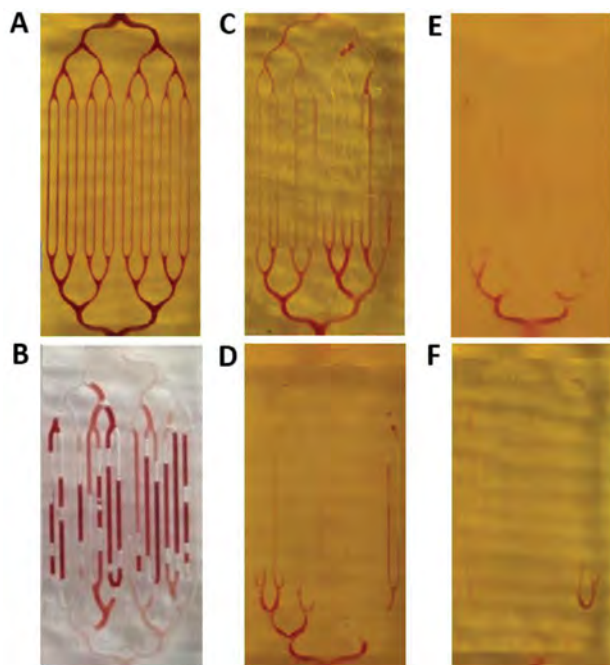


Figure 2. (A) An exemplary device under test during active blood flow. (B-F) FTD NanoClear (negative control), base PDMS Resin, 1% MPC, 1.8% PEGMA, and 2% PEG-PDMS infusion devices post-blood exposure.

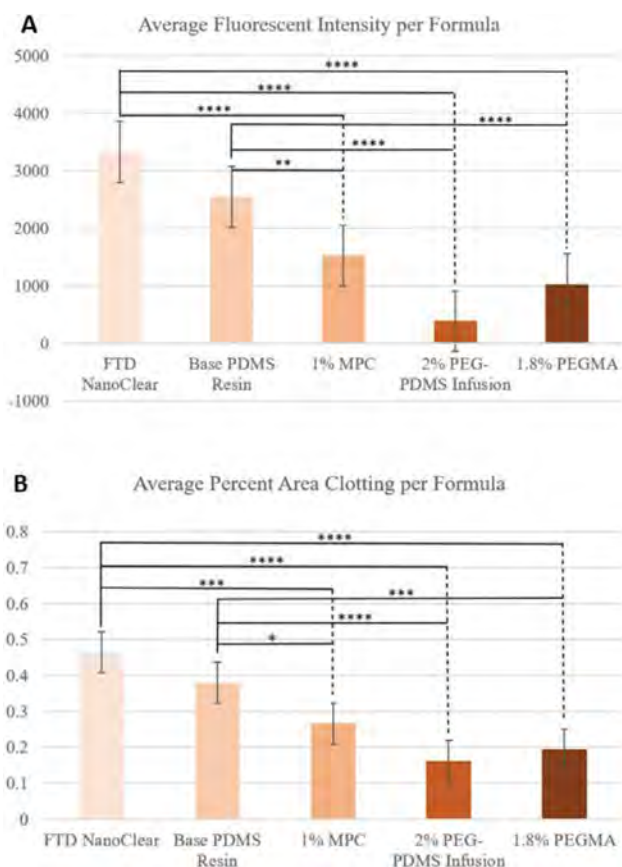


Figure 3. (A) Average fluorescent intensity and (B) Percent area clotting data comparing negative control (FTD NanoClear), Base PDMS Resin, and three experimental groups. (* = $p < 0.05$, ** = $p < 0.01$, *** = $p < 0.001$, **** = $p < 0.0001$)

BIO14

Lessons learned from Antifouling Coating-by-Priming of the Artificial Lung

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Background: The densely packed fiber bundle design of the artificial lung increases its gas exchange efficiency by dramatically increasing its surface area to volume ratio. However, the close arrangement of the fibers is a significant source for blood coagulation and the complexity of the bundle geometry makes achieving uniform antifouling coating a challenge. It was hypothesized that a solution-based coating approach involving priming of the artificial lung with coating solution can lead to a uniform antifouling activity across densely packed fiber arrangement. The rationale was that uniform coating coverage across the fiber bundle could be achieved and therefore consistent antifouling activity.

Methods: In this study, polydopamine/ zwitterionic polysulfobetaine methacrylate (pDOPA/pSBMA) was grafted onto artificial lungs (N=2) and the antifouling activities of coated bundle were evaluated. Flow effects on the antifouling activities were also studied. A two-step technique for surface modification, which included ultraviolet-oxygen plasma activation followed by pDOPA/pSBMA surface grafting was expected to improve platelet (plt) and fibrinogen (Fg) antifouling activities.

Results: Fibrinogen fouling, as measured by absorbance, on uncoated controls, coated fibers at the bundle's surface and in the middle, and coated fibers at the bundle's surface and in the middle which were exposed for fluid shear for 24hrs were 0.83 ± 0.01 , (0.36 ± 0.01 p -val=0.026), (0.38 ± 0.004 p -val=0.026), (2.64 ± 0.53 p -val=0.077) and (2.70 ± 0.72 p -val=0.077,) respectively. For platelet fouling, the absorbance values were 0.20 ± 0.003 , (0.36 ± 0.01 p -val=8.74E-11), (0.01 ± 0.02 p -val=8.74E-11), (0.02 ± 0.003 p -val=0.218), and (0.03 ± 0.01 p -val=0.218) respectively.

Conclusion: While pDOPA/pSBMA coating significantly reduced fouling in the fiber bundle, differences in coating appearance and antifouling activities of its fibers suggest bundle geometry play a role in the effectiveness of coating by priming of the artificial lung device. This warrants the optimization of the currently underexplored coating by priming process for different coating materials towards achieving optimal coating coverage critical for artificial lung thromboresistance.

BIO15

PulseSim: A Practical, Economical, Programmable Cardiovascular Simulation Platform for Ventricular Assist Device (VAD) Evaluation

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Background: The mock circulatory loop has been an integral part of Left Ventricular Assist Device (LVAD) development since its inception. Existing mock loops span a wide spectrum of complexity, functionally and cost. The most sophisticated mock loops may incorporate programmable ventricular stroke volume, heart rate, and include elements for atrial and arterial impedance as well as baroreflex regulation of afterload. However, these are prohibitively expensive for many academic labs, especially in low resourced settings. This study was performed to develop an economical mock loop that contains the key functional features.

Method: PulseSim integrates four core elements to simulate left heart and systemic circulation dynamics (Figure 1): a Left Ventricular Simulator, an Aortic Compliance Chamber, a Self-regulating Afterload component, and an Atrium/Preload Chamber. The system is mostly comprised of laser-cut acrylic, 3D-printed parts, and readily available fluid components for reduced costs and broader accessibility.

LV Simulator: comprised of a servo-driven linear actuator, driven by an inexpensive single-board computer (Arduino) that generates realistic cardiac pressure and flow waveforms. Built-in silicon Tri leaflet one-way valves (Figure 2) ensure unidirectional flow and valve resistance.

Aortic Compliance Chamber: emulates the aorta's elasticity, acting as a pulse dampener from the LV simulator and connected LVAD. It includes multiple ports for inflow, outflow, and air venting.

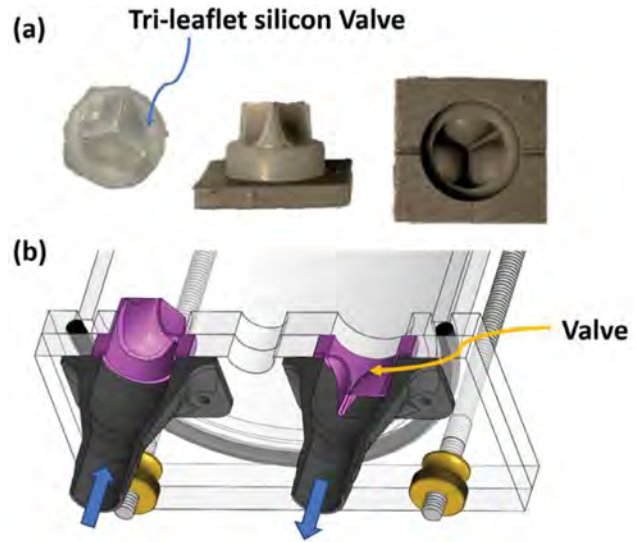
Afterload: elegantly simple pressure regulator comprised of a collapsible tube within a pressurized chamber. It replicated the body's natural baroreflex.

Atrial Chamber: provides the necessary preload pressure to the mock LV. A flexible membrane maintains consistent pressure levels, adapting to volume changes.

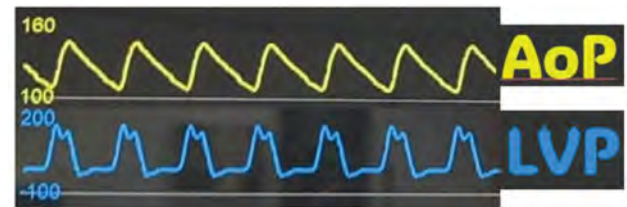
Results: PulseSim was tested by prescribing a trapezoidal position signal at a fixed beat rate of 60 bpm, to the mock ventricle, and manually adjusting the preload pressure, baroreflex pressure setpoint, which produced desired systolic and diastolic LV pressure (140/15mmHg) and aortic pressure (120/80mm) (Figure 3) that morphologically resembled physiological waveform including the arterial dichrotic notch.

Conclusion: PulseSim is a cost-effective solution for in-vitro testing of LVADs, providing versatile control of systemic hemodynamic parameters. It is easily constructed, making it accessible to laboratories worldwide.

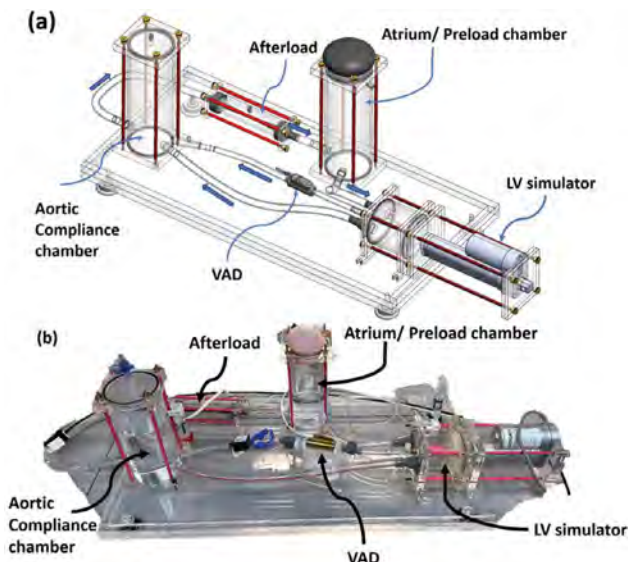
(a) PulseSim System CAD model and its components, (b) Pulsim working model



(a) Silicon molded tri-leaflet valve (b) Cross-sectional view of LV simulator valve section



Aortic (AoP) and Left ventricular (LVP) waveforms generated by PulseSim



BIO16

Adapting and validating the advancing front model to design a biofabricated lung

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Background: A biofabricated lung is being designed as a means of permanent respiratory support for patients with chronic lung disease. This lung is composed of type I collagen (COL I) parallel plates seeded with naturally anticoagulant endothelial cells on the blood side and epithelial cells on the air side to improve barrier function. However, an accurate oxygen transfer model is needed to design a compact biofabricated lung that transfers gas efficiently. Previously, Ukita et al. used an advancing front model to predict oxygen transfer (VO_2) in polydimethylsiloxane (PDMS) microchannel lungs. Here, the model has been adapted, evaluated to predict the oxygen transfer of COL I channels, and subsequently used to design biofabricated lungs.

Methods: To evaluate the model, two groups of COL I channels were cast with varying surface areas (see Table 1). To assess VO_2 , the inner lumen of the COL I channels was perfused with 0.5 and 1.1 mL/min of citrated bovine blood conditioned to AAMI venous blood conditions. Simultaneously, 100% oxygen with a flow rate equal to 2x the blood flow rate was provided over the outside of the channel. To calculate the experimental VO_2 , inlet and outlet blood samples were taken and analyzed for PO_2 , pH, and hemoglobin concentration with a blood gas analyzer. The theoretical VO_2 for each channel was calculated using the methods of Ukita et al. with the measured inlet PO_2 , pH, and hemoglobin; membrane oxygen solubility equal to that of water; and a least squares determination of the COL I oxygen diffusivity. The resulting oxygen diffusivity, D , was compared to published values, and the experimental and theoretical outlet saturations were compared. Lastly, the optimized model was used to create a family of rat-scale biofabricated lung designs with a blood flow of 38 mL/min, 40% O_2 sweep gas, VO_2 of 2.2 mL O_2 /min, wall shear stress of 15 dynes/cm², and wall thicknesses of 10, 20, and 40 μ m.

Results: The optimized COL I membrane D was found to be 2.97×10^{-5} cm²/s, which is within the expected range $0.66 \times 10^{-5} \leq D \leq 3.85 \times 10^{-5}$ based on the literature. As seen in Figure 1, the theoretical and predicted VO_2 values align well. The average percent error for the base group predictions was 8.05%, while the average percent error of the large surface area predictions was 11.5%. The priming volumes and number of COL I channels of the family of rat-scale biofabricated lungs with VO_2 of 2.2 mL O_2 /min are shown in Fig. 2.

Conclusion: The advancing front model can be adapted to model the oxygen transfer of a COL I channel. The validated model is a great asset to efficiently design a biofabricated lung that meets performance requirements and is feasible to manufacture. Future studies will focus on completing data acquisition for channels with varying surface area, wall thicknesses, and lumen heights. The model will be revised as needed.

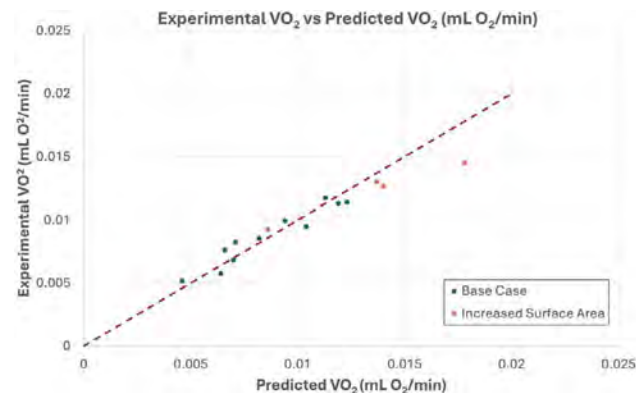


Figure 1. Experimental vs Predicted VO_2 . The base case group is shown in dark blue markers, and the large surface area group is represented by the orange points. A unity line was added in red to compare the measurements.

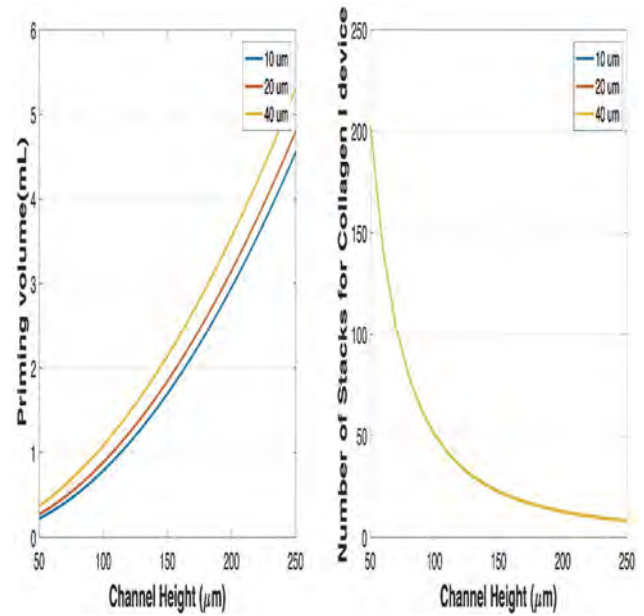


Figure 2. Sample design curves for a rat-scale lung with a 2.2 mL/min VO_2 with varying membrane thicknesses (10, 20, 40 μ m).

Table 1. Experimental Groups for Oxygen Transfer Studies

Group	Target lumen height (μ m)	Actual lumen height (μ m)	Membrane thickness (μ m)	Effective length (cm)
Base case (n=5)	150	280 $\pm$ 14.11	25.8 $\pm$ 5.33	3
Increased surface area (n=2)	150	280 $\pm$ 14.11	25.8 $\pm$ 5.33	6

BIO17

A first step towards treating incurable lung diseases with endothelial cell-based ex situ therapy

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Background: Increasing incidence of end-stage lung disease, for which lung transplantation is the only treatment option, is accompanied by growing discrepancy between organ donors to recipients. To expand the donor pool, ex situ lung perfusion (ESLP) has been developed, in which lungs are physiologically ventilated and perfused. Their advantages are increasingly used for the establishment of innovative therapeutic strategies that would be either harmful to other organs, less efficient or impossible if performed in vivo. Given that the endothelium plays an important pathogenetic role in many lung diseases (e.g. pulmonary arterial hypertension (PHT)), we established an endothelial cell-based ex situ therapy in which diseased native endothelium can be supplemented or even replaced by functional endothelium.

Methods: Using different ESLP-relevant preservation solutions and concentrations of 17 β -estradiol (ES), disintegration of the native endothelial monolayer (EM) with subsequent integration of labelled endothelial cells (ECs) and consecutive regeneration of the entire EM was analyzed in vitro. Viability was investigated by calcein staining, regeneration of cell connections by CDH5 immunofluorescence and barrier function by transwell assays. Endothelial cell-specific nitric oxide, activation and thrombogenic state markers, also physiological reactivity to TNF α were analysed by qRT-PCR. With regard to translation, analyses were performed with human and rat ECs. Determined optimal protocol was applied in ex-situ perfused rat lungs. After disintegration, perfusion solution enriched with labelled ECs was administered. At the end of the experiment, labelled, non-integrated ECs in the perfusion solution were quantified by FACS. To detect integrated ECs, lungs were fixed and subjected to either cryosectioning or optical clearing for light sheet microscopy (LSM).

Results: All perfusion solutions led to endothelial disintegration, enhanced by concentration-dependent ES addition. CDH5 provided evidence for integration of vital, labelled ECs into the native monolayer, whose confluence and barrier function were best regenerated in Steen solution. Gene expression analyses confirmed a physiologically non-inflammatory and antithrombotic eNOS-producing cell layer. FACS analyses showed that <1% of the labelled ECs were flushed out of the lung after ex situ integration. Labelled ECs could be detected in the whole rat lung by LSM, also confirming their localization in the pulmonary microvasculature.

Conclusion: General feasibility of this innovative ex situ therapy was demonstrated and will be established for special applications, such as the use of genetically modified ECs (e.g. eNOS-producing ECs in PHT), as well as the transfer to other ex situ-perfused organs (e.g. LAMA4 in DCM). This could enable not only an expansion of the donor pool through ex situ therapy of marginal organs, but also autologous ex situ therapy that makes transplantation unnecessary.

BIO18

An ECMO Sweep Gas Controller with Closed-Loop Feedback

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Study: Current Extracorporeal Membrane Oxygenation (ECMO) systems rely on hospital staff to make adjustments to the sweep gas of the artificial lung (AL) to control patient blood CO₂ levels. However, these changes are imprecise and require periodic blood draws, potentially leading to large changes in blood CO₂ levels, particularly when the patient is ambulatory or undergoing physical therapy. An ECMO system that automatically and rapidly adjusts the sweep gas to precisely control patient blood CO₂ would reduce staffing effort, increase patient comfort, and improve patient activity and rehabilitation. We previously reported a system that autoregulates pump driven air flow through an AL. This work reports an ECMO sweep gas controller that uses up to three pressurized gas sources (from gas cylinders) that could greatly expand potential clinical applications.

Methods: An integrated system (Fig. 1) was developed that automatically modulates gas flow rate through any commercially available AL in response to changing metabolic rates and blood CO₂ levels. The CO₂ concentration in the AL exhaust gas (EGCO₂) is sampled (CO2Meter GC-0017) as an analog for blood pCO₂ measurements. The system adjusts the sweep gas through the AL in real-time through gas flow controllers (Sensirion SFC5500) to achieve a target EGCO₂ (tEGCO₂) value using a proportional integral derivative (PID) controller.

One liter of heparinized bovine blood was conditioned to venous blood (pCO₂: 36-127 mmHg), and used for *in-vitro* tests (Fig. 2). Different metabolic levels were simulated by changing the pCO₂ in the sweep gas through the conditioning lung to 36, 69, and 127 mmHg. Controller performance was assessed under different tEGCO₂ values (10, 20, 30, and 40 mmHg) with 1.0 L/min blood flow rate. It was also tested with different blood flow rates (0.5, 1.0, 2.0, and 4.0 L/min) with fixed tEGCO₂ at 20 mmHg. For comparison, tests were performed with 1:1 blood:gas ratio to simulate a standard manually operated ECMO system.

Results: The integrated controller responded to metabolic changes to maintain a specified EGCO₂ when the negative feedback system was in effect. Under most scenarios, it responded within 2 min, and stabilized within 5 min. (Figure 3a) The controller achieves this by increasing sweep gas flow when blood pCO₂ (and thus EGCO₂) increases, thereby removing more CO₂ when blood pCO₂ increases. (Fig. 3). The variation of pre- and post-oxygenator pCO₂ as a function of simulated metabolic rate was less with the control system active than compared to a fixed 1:1 blood:gas ratio for all tests (Fig. 4).

Conclusions: This ECMO system uses a negative feedback algorithm to automatically respond to changes in patient metabolism, reducing the fluctuation of blood pCO₂ compared to the current standard of fixed sweep gas. This can be used to reduce the monitoring requirements for patients (blood sampling), and better maintain patient comfort during periods of rest or physical exertion.

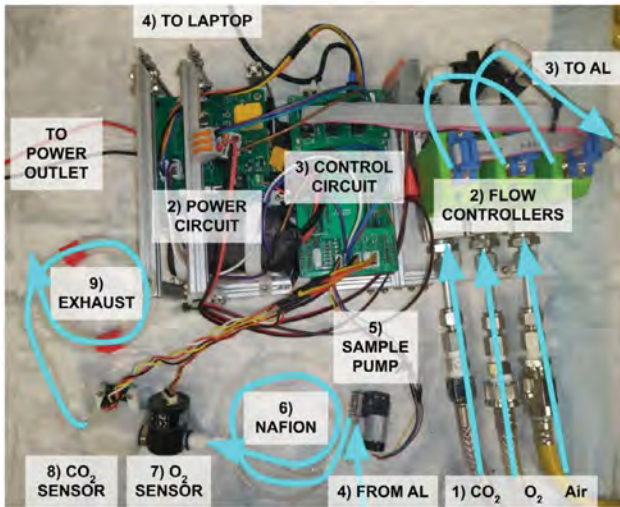


Figure 1. Sweep Gas Controller (partially disassembled to show the various components). (1) Three gas inlets (CO_2 , O_2 , and N_2); (2) Three gas flow controllers; (3) Outlet of sweep gas to the AL; (4) AL sweep gas exhaust; (5) Sample pump (samples some the exhaust gas via side stream sampling); (6) The sample travels through Nafion tubing where moisture is removed; (7) O_2 sensor; (8) CO_2 sensor; (9) Loop of tubing to prevent backflow contamination.

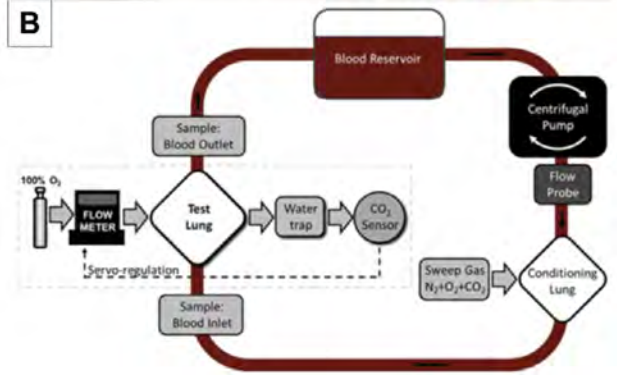
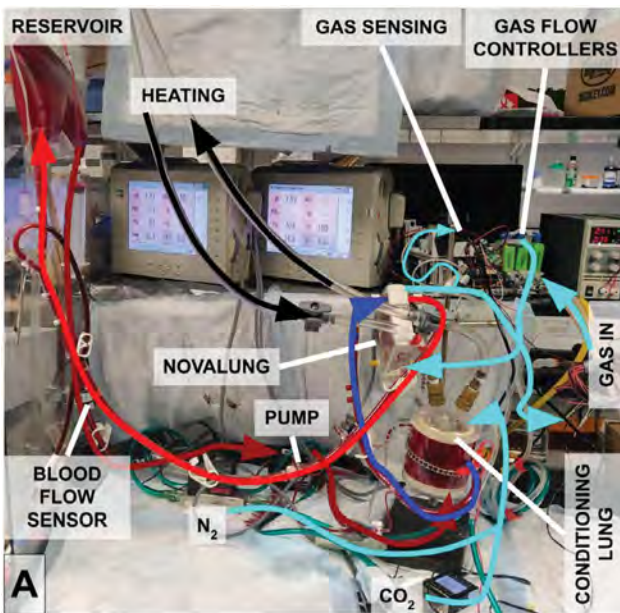


Figure 2. In-vitro testing setup. Light blue arrows denote gas flows, and red and dark blue arrows denote blood flows. The ratio of $\text{CO}_2:\text{N}_2$ in the sweep gas of the conditioning lung was varied to challenge the test lung (Novalung) and sweep gas controller. The exhaust gas from the Novalung was sampled by the control system to measure EGCO_2 .

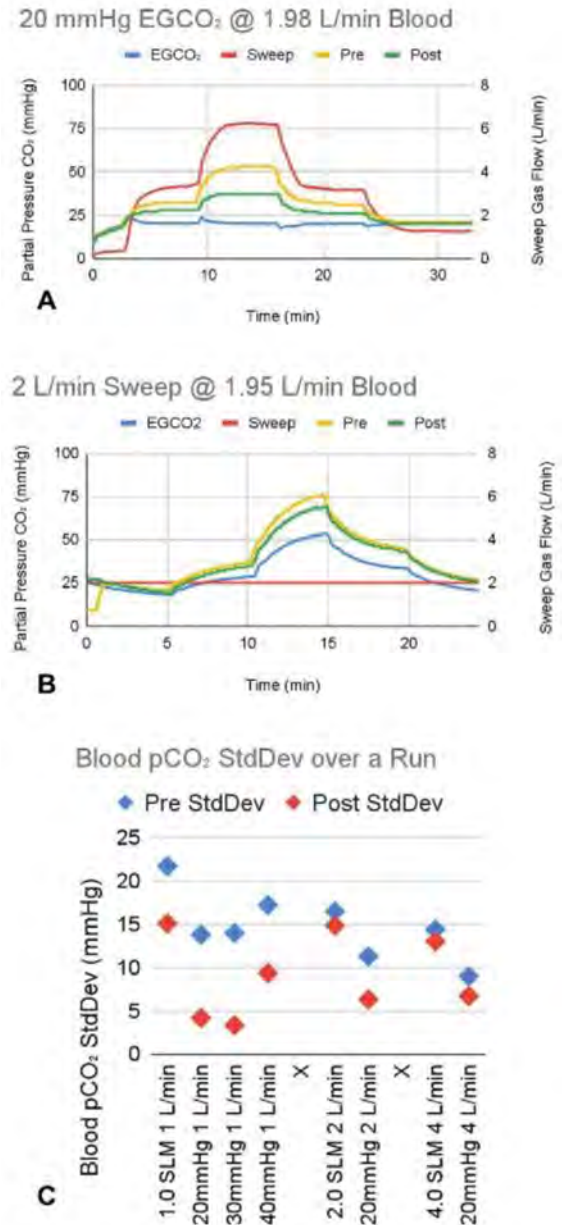


Figure 3. Experimental plots of pCO_2 over time (A) Sweep gas controller ON (fixed tEGCO_2), sweep gas flow (red line) is automatically increased to keep EGCO_2 constant. Since higher blood pCO_2 values typically result in higher EGCO_2 values, this keeps post-AL blood pCO_2 (green) from varying as much as it otherwise would. Since the blood circuit is closed, the pre-oxygenator pCO_2 (yellow) also has less variance; (B) Sweep Gas Controller OFF, there is a greater variance in both pre-AL and post-AL blood pCO_2 . (C) Standard deviation of all the recorded pCO_2 values during a run can be used to quantify the stability of the pCO_2 . For each given blood flow rate, the fixed EGCO_2 method always results in a lower standard deviation than the equivalent Fixed 1:1 Blood:Sweep method. (eg. 20 mmHg @ 1 L/min vs 1 SLM @ 1 L/min, or 20 mmHg @ 4 L/min vs 4 SLM @ 4 L/min.)

BIO19

Validated Computational Model Predicts Impact of Flow Rate and Dialyzer Choice on Bilirubin and Cholic Acid Removal by Albumin Dialysis

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Purpose of Study: Protein bound toxins (PBTs) are involved in liver failure, kidney failure, cholestasis, genetic disorders, and other diseases. The removal of PBTs by standard dialysis is limited since the bound fraction is not dialyzable using standard dialysate. Adding albumin to the dialysate is a well described way to remove PBTs. This is usually done in a “closed-loop” mode, so albumin is recirculated instead of being discarded. An experimentally validated theory to predict the outcome of “closed-loop” albumin dialysate for different dialyzers, flow rates, and specified toxins would improve the understanding and prescription of albumin dialysis treatment.

Methods Used: We designed a computational model of diffusion and convection of fluid and toxin across the dialyzer membrane. The model has two parameters to fit: albumin binding affinity for the toxin of interest and dialyzer mass transfer-area coefficient (KoA) of the toxin of interest. Table 1 summarizes the two setups. Net ultrafiltration was zero in all tests, but the model accounts for ultrafiltration and backfiltration within the dialyzer. Blood analog solution was created using dialysate, bovine serum albumin (BSA), bilirubin, cholic acid (CA), indoxyl sulfate, manganese, copper, and creatinine. These toxins bind BSA at different sites, so competition between them does not alter the results. pH was adjusted within the 7.2-7.5 range. Bilirubin and BSA were measured by spectrophotometry. CA was measured by mass spectrometry. The model parameters were fit using Setup 1. Then, the outcome of Setup 2 was predicted. Next, the effect of changing dialysate flow rate in Setup 2 on bilirubin removal was studied.

Results: The model predicted the equilibrium bilirubin concentration using Setup 2 with the F3 dialyzer to within 5.04% from parameters fit using Setup 1 data with the F6HPS dialyzer. It predicted CA concentration in Setup 2 to within 12.6% accuracy. It predicted no impact on equilibrium bilirubin concentration from dialysate flow rate changes between 1.5 mL/min and 800 mL/min. This prediction was accurate within 2.94% for a 20 mL/min flow rate, compared to the 150 mL/min flow rate in Setup 2. Testing of other flow rates is ongoing.

The model predicted longer time to equilibrium with slower flow rates. It underestimates time to reach equilibrium in all conditions tested. Work is ongoing to better fit kinetics, in addition to the equilibrium value.

Summary of Conclusions: A model of albumin dialysis predicted the effect of changing flow rates and dialyzers on equilibrium bilirubin and CA concentrations in *in vitro* experiments.

BSA Dialysis Setups

	Setup 1	Setup 2
Solution Volume (mL)	500	200
Blood Flow Rate (mL/min)	180	150
Dialysate Flow Rate (mL/min)	90	150
Blood and Dialysate BSA Concentration (g/dL)	2	2
Dialyzer	F6HPS	F3

BIO20

A Computational Multiscale Method To Determine The Three-Dimensional Toxin Concentration Distribution In A Hemodialyzer

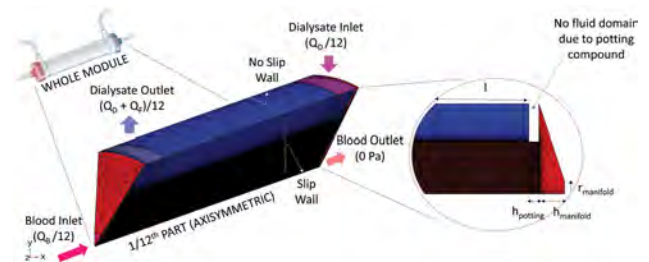
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Purpose of Study: Determining the toxin concentration drop in the blood flowing along each of the numerous hollow fibers in a hemodialyzer is crucial to understanding the dialyzer’s clearance performance and improving its design, but no *in vitro* or *in silico* method has existed to do so.

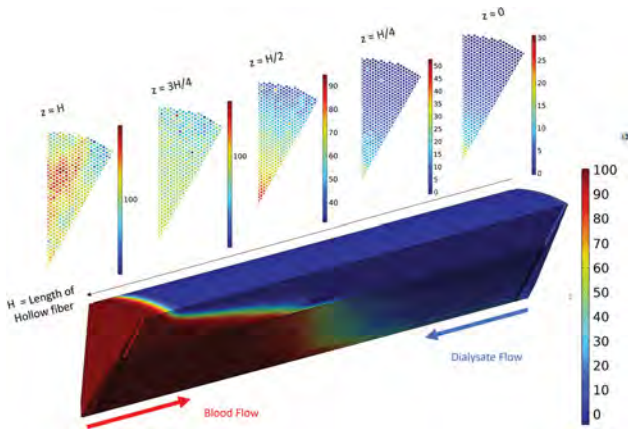
Methodology: In this study, we put forth a computational multiscale method that enables the determination of the toxin concentration profile in the axial and radial directions in a hemodialyzer. The method assumes the dialysate flow is axisymmetric and divides the hollow fiber module cross-section into three annular rings of equal cross-sectional area. The blood is allowed to flow through the lumen region of only one of those rings at a time while dialysate flows through the shell region of all the rings. The blood and dialysate flow in the ring of interest are computed as free flows while the dialysate flow in other rings is computed as porous media flows. This approach allows the computation of the flow and concentration fields in the entire three-dimensional hemodialyzer at a reduced computational cost compared to brute force, single-scale methods. As a case study, we used the geometric parameters of a high-flux commercial hemodialyzer (the Baxter CT190G) consisting of 12,000 hollow fibers, each of inner diameter 200 μm with thickness 15 μm and length 240 mm inside a module of diameter 35 mm. The blood flow rate in the study was 120 mL/min and the dialysate flow rate was 500 mL/min mimicking clinical operating conditions.

Results: We found that the peak dialysate toxin concentration was located upstream of the dialysate outlet, consistent with previous *in vitro* and numerical studies. For the innermost of the three rings, the model toxin remained concentrated near the dialyzer axis. The toxin concentration at the blood outlet remained as high as 30% of the inlet value in fibers near the centerline of the dialyzer and fell to almost zero at the periphery, consistent with the effects of dialysate flow channeling. In the middle ring, however, the zone of higher toxin concentration reversed from the outer periphery to the inner periphery along the blood flow direction, which could be a result of internal filtration effects.

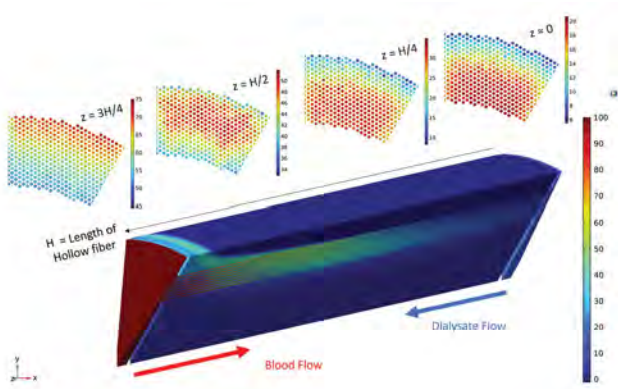
Summary: We put forth a new computational multiscale modeling approach that enables the calculation of the three-dimensional distribution of toxin concentrations in a full-scale hemodialyzer. This modeling approach can be used to develop a better understanding of hemodialyzer flow and clearance physics and may aid in determining optimal dialyzer designs and operating conditions.



The computational domain is a 1/12th segment of the whole hollow fiber module due to the assumption of axisymmetry. Realistic inlet and outlet manifolds and radial dialysate flow at the entry and exit are incorporated.



The axial and radial toxin concentration distribution in the blood flowing through the hollow fibers in the innermost ring in a model of the Baxter CT190G high-flux dialyzer.



The axial and radial toxin concentration distribution in the blood flowing through the hollow fibers in the middle ring in a model of the Baxter CT190G high-flux dialyzer.

BIO21

Custom 3D Printed Cannulas for Extracorporeal Life Support in Preterm Neonates

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Purpose: Extracorporeal life support (ECLS) currently cannot be performed in extremely premature infants (<2 kg) because there are no commercially available drainage cannulas small enough for these patients. 3D printing promises a cost-effective method to create custom cannulas based on the patient's small size and unique vascular anatomy. Here, we explore three manufacturing methods to produce novel <6Fr drainage cannulas.

Methods: Three methods were used to manufacture the cannulas: cannulas were printed on the Form 3/3B SLA printers (17 μ m resolution, Formlabs' Flexible 80A resin). Cannulas with a hard reinforcement to discourage collapsing were printed on a Stratasys J750/J850 printer (50 μ m resolution, Agilus30 with VeroClear reinforcement). A Medtronic 6Fr, 50 mm infusion cannula with an internal spring and 3D-printed J750 cannulas were converted into drainage cannulas via a 40W, 10.6 μ m CO2 laser drill. Cannulas largely used a "simple" design (6Fr, 60 mm long) and an "expanding" design (6Fr, 90 mm long) (Fig. 1). Testing focused on the Form 3 cannulas. They were tested in vitro by simulating an ECLS circuit consisting of a drainage cannula connected to a centrifugal pump, flow sensors, and transducers in a water-glycerol mixture to simulate the viscosity of blood. The corresponding pressure loss was measured at varying flow rates up to the point of collapse.

Results: The Form 3/3B cannulas were manufactured successfully, albeit with slight external surface roughness from supports (Fig 2a, 2b). The J750/J850 cannulas experienced splitting at the base and tip in the higher shore ranges, although this was reduced with an oval cross-section (Fig 2c, 2d). There was no noticeable effect from the mechanical reinforcement. The laser drill, while successful, left discoloration, residue, and potential exposure of steel reinforcement (Fig 2e, 2f). During in vitro testing, Form 3 cannulas had an average pressure loss of 39 mmHg at 100 mL/min and collapsed at 80 mmHg at 185.8 mL/min. The Form 3B cannulas had an average pressure loss of 42.3 mmHg at 100 mL/min and collapsed at 85.7mmHg at 165mL/min.

Conclusion: Cannulas 3D-printed on the Form 3/3B had suitable flow rates for ECLS in extremely premature infants and are the most feasible to manufacture compared to the other manufacturing methods. This method can also likely be implemented in other use cases, such as small animal research.

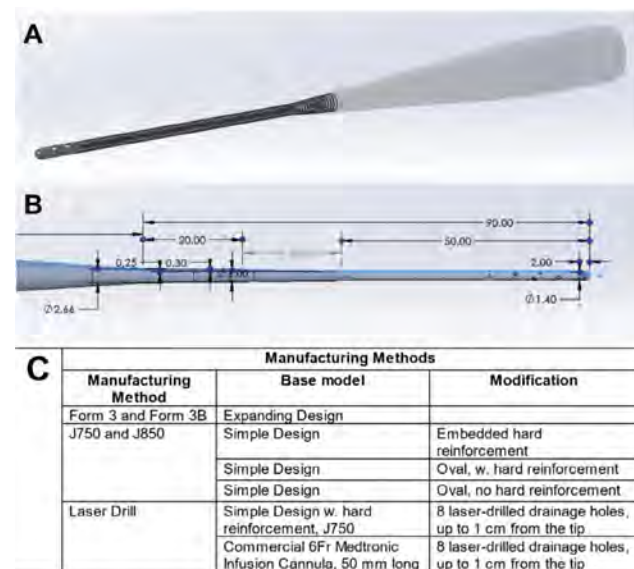


Figure 1. Cannula Design and Manufacturing Methods (A) Simple design, 60mm long, 6Fr tapering to 4Fr at the tip, with 8 side holes up to 1 cm from the tip; **(B)** Compound design, 50mm 6Fr outer diameter section with a tapered tip + 40mm 8Fr section that

can be advanced as the patient grows, for a total of 90 mm, with 16 side holes up to 2 cm from the tip; **(C)** Manufacturing methods

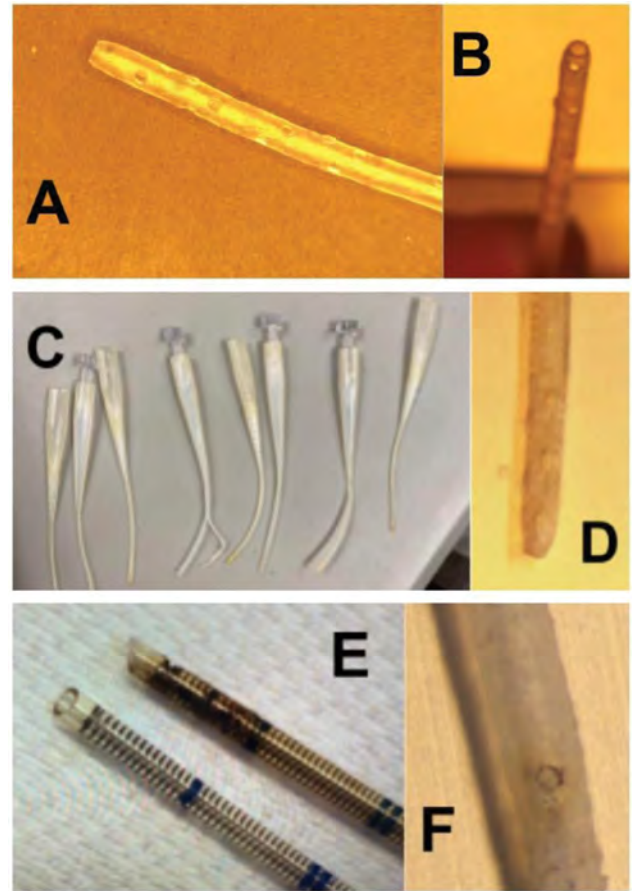


Figure 2. Cannula Manufacturing Results (A) Cannula manufactured by a Form 3; **(B)** Cannula manufactured by a Form 3; **(C)** Cannulas manufactured by a J850; some cannulas have split during manufacturing; **(D)** A closeup of a cannula printed by a J850; **(E)** Medtronic cannulas had drainage holes added by a laser drill; **(F)** Cannulas printed by a J750 had drainage holes added by a laser drill

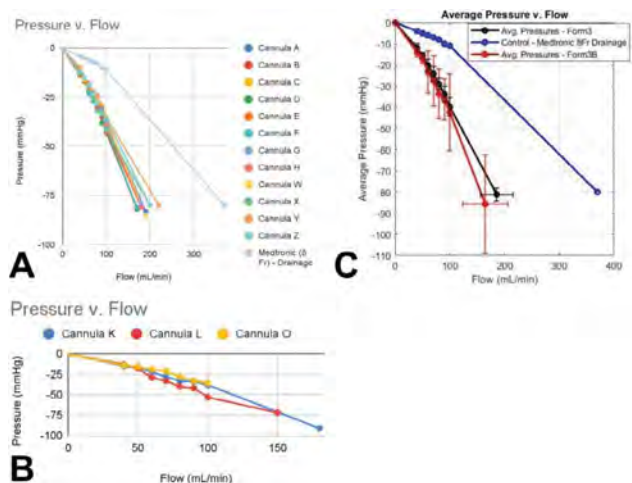


Figure 3. Cannula Testing Results (A) Flow rates and pressure data of the 12 Form 3 cannulas; **(B)** Flow rates and pressure data of the 3 Form 3B cannulas; **(C)** Flow rates and average pressure data of Form 3 and Form 3B cannulas

BIO22

Less Invasive Device Therapy for Diastolic Heart Failure: Early *In Vivo* Assessment of Technology

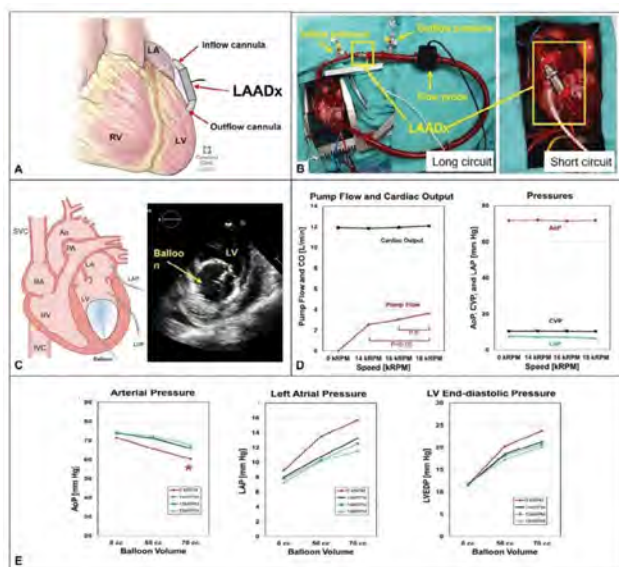
Chihiro Miyagi, Taiyo Kuroda, Barry D. Kuban, Christine R. Flick, Anthony Polakowski, Jamshid H. Karimov, Kiyotaka Fukamachi; *Biomedical Engineering, Cleveland Clinic Lerner Research Institute, Beachwood, Ohio, United States*

Background: A less invasive left atrial assist device (LAADx) is a novel implantable, extracardiac, blood pump concept (Fig. 1A) intended for treatment of diastolic heart failure (DHF). We report the results of a pilot *in vivo* assessment of the LAADx concept in acute bovine models with/without simulated DHF conditions.

Methods: A mixed-flow pump capable of 4 L/min at 80 mm Hg was used as a working LAADx prototype and was implanted in 4 healthy calves (87 ± 8 kg) through a left thoracotomy. Without going on bypass, the pump inflow was placed in the left atrium (LA), and the outflow cannula in the left ventricle (LV). Subsequently, the LAADx was connected to both cannulas (Fig. 1B) and operated at various speeds under dynamic conditions, produced by a custom-made intraventricular balloon. Inserted from the LV apex and inflated from 0 mL to 70 mL (Fig. 1C), the balloon enabled simulation of DHF conditions by reducing the LV filling volume and increasing the LV wall stiffness.

Results: The LAADx ran as expected during the experiments. Hemodynamics were recorded over the full range of pump operational speeds (from 14,000 to 18,000 rpm). The pump flow reasonably increased from 2.3 to 3.3 L/min (Fig. 1D). Under simulated DHF conditions, there were increases in mean LA pressure and LV end-diastolic pressure, and a decrease in the aortic pressure, which were mitigated with the LAADx support (Fig. 1E).

Conclusion: The LAADx concept demonstrated the intended hemodynamic effects in a large animal model with simulated DHF conditions.



BIO23

Multigraft-Bac: An Electrospun PEUU-Based Tissue-Engineered Vascular Graft with Antimicrobial Properties for Infection Control

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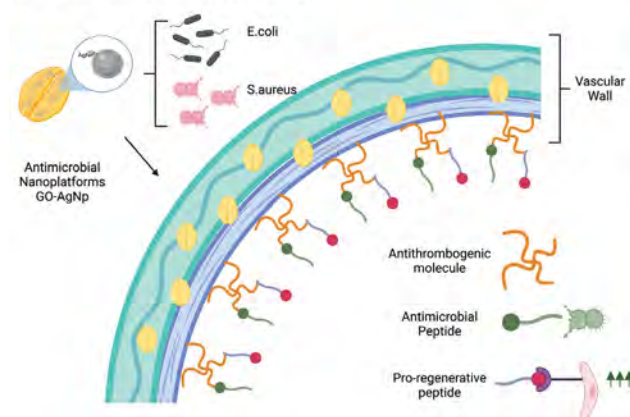
Background: Infections associated with vascular grafts represent a major challenge at the clinical level, considering that they lead to complications related to sepsis, amputations, increased bacterial growth sites and even death. These adverse effects contribute to morbidity and mortality rates of 52% and 58%, respectively. The proposed study exposes the tissue-engineered polymeric vascular graft (TEVG) Multigraft-Bac, a novel alternative with molecules that provide antimicrobial properties.

Methods: A bilayer TEVG with polyester-urethane-urea (PEUU) as the base polymer was fabricated using the electrospinning technique. The inner layer was functionalized with an anticoagulant spacer, a cell adhesion peptide and an antimicrobial molecule, while the outer layer contained graphene oxide (GO) nanoplatelets with silver nanoparticles that help strengthen the antimicrobial action of the graft. The correct functionalization of the molecules used was validated through physicochemical assays such as Fourier transform infrared spectroscopy (FTIR) and thermogravimetric analysis (TGA). MTT and hemolysis tests provided insight into the biocompatibility of TEVGs. Platelet behavior was validated through aggregation and LDH assays. Antibacterial activity against *S. aureus* and *E. coli* was quantified by exposing the graft to a diluted bacterial solution and counting the number of colonies present.

Results: The developed TEVG has a diameter of 2.5 mm and a wall thickness of 0.2 mm. The luminal layer is associated with more compact fibers that prevent fluid loss, as opposed to the adventitial layer with spaced fibers that favor cell regeneration. The graft demonstrates excellent biological properties with cell viability percentages greater than 80% and hemolysis levels of less than 1%. Additionally, TEVG possesses antithrombotic features that maintain platelet aggregation levels at less than 25%, as well as favoring cell adhesion. The bacteriostatic and bactericidal potential of the graft is manifested against *S. aureus* and *E. coli* strains in comparison with the PEUU control where no relevant antimicrobial effect is evidenced.

Conclusion: This work incorporates excellent biological properties with considerable antimicrobial activities in the lumen and adventitia of a TEVG. Undoubtedly, the proposed graft has promising potential in antibacterial therapies and treatment of mycotic aneurysms. Further studies intend to perform a carotid interposition procedure in porcine animal models to validate the extrapolability of the experimental results found under controlled conditions from a clinical point of view.

Antimicrobial Tissue Engineered Vascular Graft



BIO24

Daily-ssist: A Complementary Dialysis Recycling System for Water Conservation

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Background: Hemodialysis (HD) is the dominant form of blood purification employed for patients with end-stage renal disease. Operationally, modern HD systems utilize a hollow fiber kidney system in which blood is perfused thru while dialysate is cross perfused over and surrounding the fiber bundle allowing for fluid, electrolyte and waste exchange, with equilibration based on the tonicity and ion concentration of the dialysate. Unfortunately, present systems require access to a large source of water and dialysate, are hospital or clinic-based, and non-portable. Here we examined the possibility of creating a system – “Dialy-ssist” to recapture dialysate and water, to allow for its reuse. Our long-term goal is to develop a system applicable to hospital/clinic systems; evolving home portable systems by freeing up the dependence and use of significant water supplies. To start, we will begin testing our dialysate capture and water conservation system, for filter saturation and overall efficiency.

Methods: A recycle system using activated carbon, urease, zirconium hydroxide, zirconium phosphate, amberlite IR-252, and amberlite IR-420 was re-evaluated. Modeling was performed to determine theoretical purity of the removal of toxins from dialysate including urea and creatinine and ions such as Na⁺ and Cl⁻. Wet *in vitro* experiments are planned to confirm the achieved purity from theoretical calculations and the amount of materials needed to reach the desired purity. For these experiments, a proxy spent dialysate was created and ran through the Daily-ssist system for 3 hours to stimulate the average length of dialysis. Samples were taken every 5 minutes for the first hour and every 15 minutes for the remainder for a purity assessment using conductivity and pH.

Results: Further refinement of the modeling revealed that the addition of urease catalyst with an initial base of 402 g of activated carbon can effectively remove 100% urea, creatine, and ureic acid based on proxy spent dialysis concentrations. Langmuir isotherm equations modeled absorption for activated carbon, zirconium, and DI Resin. Results showed DI Resin completely absorbs salts and bicarbonate compounds, with catatonic and anionic resin removing a total of 29.21g and 26.26g respectively.

Conclusions: Improvements made in modeling have allowed for a greater understanding of how the Dialy-ssist water filtration system is able to remove harmful substances from wasted dialysate, with nearly 100% removal of urea, creatine, uric acid, and ionic compounds. These values suggest this system may be clinically viable, but more testing will be needed. Through further experimentation, proper filter scaling will be found, allowing for system optimization and potential removal of redundant filters. This will also aid in determining just how much water can be saved for reuse in medical treatment.

BIO25

Evaluating Heartbeat Synchronized Speed Modulation of a Continuous Flow Left Ventricular Assist Device Using a Mock Circulatory Loop

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Study: Left ventricular assist devices (LVAD) have significantly improved as a treatment for advanced heart failure. However, current continuous flow LVADs (CF-LVAD) create flow that is counter to the natural pulsatile flow of the circulatory system leading to decreased pulsatile blood flow in circulation which is linked to increased risk of gastrointestinal bleeding. This study focuses on using sensor input to modulate the speed of a CF-LVAD in synchrony with the heart rhythm. Using a Frank-Starling controlled mock circulatory loop (MCL) the hemodynamic response of speed modulation is evaluated.

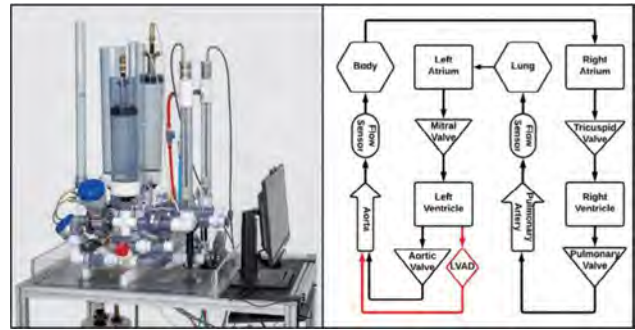
Methods: A 3D printed centrifugal CF-LVAD driven by a brushless DC motor was used. An algorithm was created to control the CF-LVAD speed using left ventricle pressure sensor input to time the speed changes. The CF-LVAD controller and the MCL controller ran independently from each other. The CF-LVAD inlet and outlet were attached to the MCL left ventricle and aorta respectively. The MCL was set to a severe heart failure condition with a heart rate of 60 BPM, and a 40% glycerol water mixture was used to match blood's viscosity.

A baseline with no LVAD, and three CF-LVAD cases were tested. In single speed flow, the pump ran at a set speed of 2200 RPM during the entire cardiac cycle. The speed was set to reach a cardiac output of 6 L/min. In co-pulse synchronized, the LVAD reached a peak speed of 2600 RPM during systole and a minimum speed of 1900 RPM during diastole. In counter pulse synchronized, the LVAD reached a minimum speed of 2000 RPM during systole and a peak speed of 2500 RPM during diastole. The minimum speed modulation speeds were set to prevent backflow through the CF-LVAD. The peak speeds were set to reach an average cardiac output of 6 L/min.

The MCL was run at baseline and the three CF-LVAD cases for two minutes each. The aortic pressure, total cardiac output, and left ventricle volume and pressure were measured and recorded using the MCL sensors.

Results: The cases with a CF-LVAD increased the total cardiac output to at least 6 L/min from the baseline cardiac output of 3.4 L/min. They also decreased the average left ventricular volume by at least 100 mL from the base line of 228mL. In the left ventricle PV loops the three CF-LVAD cases are shifted to the left compared to the baseline. The baseline case had the largest pulse pressure, followed by the co-pulsed synchronized CF-LVAD, the single speed CF-LVAD, and the counter pulsed synchronized CF-LVAD.

Conclusion: All three CF-LVAD cases increased the total cardiac output and unloaded the heart. By using co-pulse synchronized speed modulation on a CF-LVAD the aortic pulse pressure was over double the aortic pulse pressure of the two other CF-LVAD cases, and reached 87% of the baseline case aortic pulse pressure. The co-pulse synchronized speed modulation achieved increased cardiac output, unloaded the left ventricle, while maintaining pulsatile flow and pulse pressure closer to the physiological norm.



Pneumatically powered MCL picture and diagram. Each heart chamber and the pulmonary and aortic arteries have pressure sensors. Each ventricle has a volume sensor. Diagram shows where the LVAD is attached.

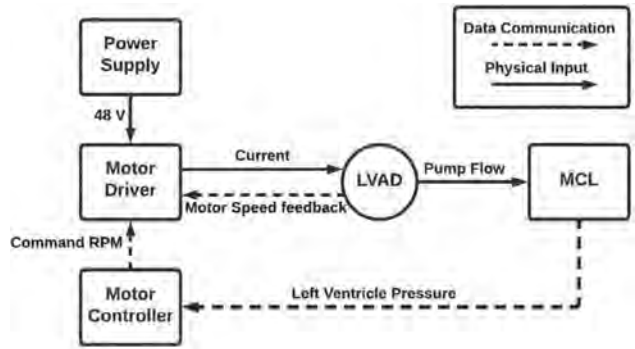
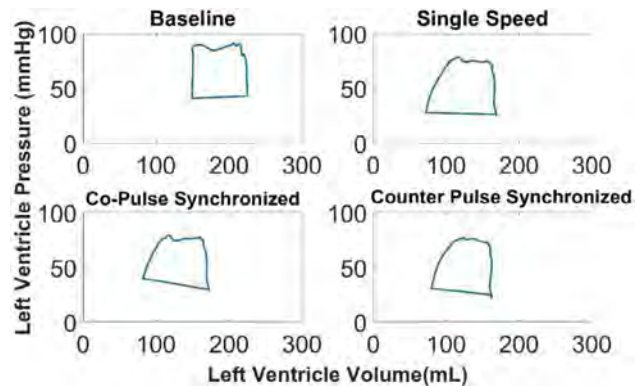


Diagram of the speed modulation control.



Left ventricle pressure volume loops for the four test cases.

Test Case	Aortic Pulse Pressure (mmHg)	Total Cardiac Output (L/min)	Average Left Ventricular Volume (mL)
Baseline (no LVAD)	20.7	3.4	228
CF-LVAD Single Speed	8.4	6.1	124
CF-LVAD Co-Pulse Synchronized	18.0	6.0	119
CF-LVAD Counter Pulse Synchronized	7.6	6.1	128

BIO26

Optimizing Aortic Hemodynamics for LVAD Therapy Using Evaheart2 Pump Speed Modulation

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Study: The absence of a functioning aortic valve (AV) and lack of trans-AV flow can lead to aortic root thrombus (ART) for LVAD patients. ART has been reported in a significant proportion of LVAD patients with closed AV and can potentially lead to devastating thromboembolic complications. This study investigates the benefits of pump speed modulation (PSM) in the EVAHEART2 (EVA2) LVAD, currently undergoing clinical trials, to optimize aortic root and aortic arch hemodynamics, including the benefits of AV opening.

Methods: We used a patient-derived anatomically accurate aortic arch model with a virtually anastomosed 14 mm outflow graft to the ascending aorta. High-fidelity simulated angiograms were obtained using 3D computational fluid dynamics (CFD) simulations for over 15 clinically relevant scenarios to model flow through the outflow graft and the AV. Customizable EVA2 PSM waveforms were incorporated to enable increased flow pulsatility and AV opening. Using novel angiographic parametric analysis for the two-fluid model, the simulated angiograms were analyzed for quantifying the flow patterns and washout from the aortic root, ascending aorta and aortic arch. We also injected and tracked thousands of simulated platelets using custom particle tracking approaches. The angiographic, hemodynamic, and platelet metrics were combined to estimate the relative thrombogenic potential of each scenario.

Results: Our analysis demonstrates that the aortic root and arch washout is strongly dependent on baseline flow rate, flow pulsatility, and flow through the AV. For a baseline flow of 4 L/min without PSM, 72% of blood from the aortic root region was washed out within 5 s. Activating PSM for the same average flow of 4 L/min increased the pulsatility index from 12% to 39%, washing out 80% of the blood from the aortic root region within 5 s (Figure 1b). A higher baseline flow of 8 L/min resulted in a washout of over 80% within 4 s with and without PSM activation. AV flow had the most significant positive impact on washout, with the aortic root thoroughly washed out within 2 s, even for a reduced AV flow of 0.9 L/min (Figure 1c). Angiographic metrics indicate a mean transit time of approximately 4.5 s in the aortic root for the 4 L/min case without PSM (Figure 1d), and shorter durations for the PSM cases.

Summary: In our study, we utilized novel two-fluid simulated angiograms to quantify the aortic root and arch washout for LVAD patients with the EVA2 device. Washout was strongly dependent on baseline flow and pulsatility, which can be incorporated using customizable PSM settings for the EVA2. Increased pulsatility in the outflow graft due to PSM improves washout, even if the AV does not open. Partial flow through the AV significantly benefited hemodynamics, achieving washout within a few cardiac cycles. PSM can be optimized for improving AV functionality and aortic root washout for EVA2 patients, reducing the risk of ART, and improving patient outcomes.

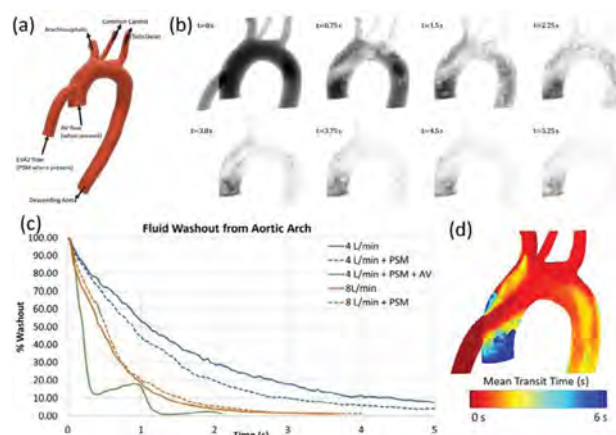


Figure 1. (a) Schematic of hemodynamic analysis setup for simulated angiogram CFD simulations (b) Simulated angiogram montage of fluid washout from aortic arch for baseline flow of 4 L/min with PSM activated showing most of the fluid from aortic root washed out within 6 seconds (c) quantitative washout analysis for five clinically-relevant cases with PSM and AV flow, indicating benefit of PSM and AV flow to achieve faster washout (d) Mean transit time of blood within aortic arch for baseline 4 L/min case without PSM showing distribution of slow moving blood in aortic root, 90% of which gets washed out after 6 seconds

BIO27

Novel Neural Network-based Hyper-resolution Flow Field Prediction to Assess Ventricular Hemodynamics for LVAD Therapy

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Purpose of Study: LVAD therapy for heart failure is increasing; however, there is an unmet clinical need for technologies that allow for an accurate, detailed, and quick resolution of the 3D flow profiles inside a left ventricle (LV) with an implanted LVAD. CFD provides high fidelity flow information, but this technique is time consuming and resource intensive. Alternatively, ultrasound can provide low-resolution flow information, but this is noisy and only provides information for one flow direction. We use novel neural networks (NN) to use unidirectional flow as input to obtain 3D hyper-resolution flow profiles.

Methods: 9 patient-derived LV geometries were implanted with LVAD inflow cannulas using virtual surgery. 47 different time-varying intraventricular flow profiles were generated by varying mitral valve inlet flow conditions via high-fidelity computational fluid dynamics (CFD) simulations in ANSYS Fluent, providing training and ground truth data. The CFD-derived 3D flow profiles were sampled to 5% of data density to simulate noisy, low-resolution data (such as from ultrasound). A 3D convolutional U-Net NN was built to map the sparse flow profile to a full-resolution detailed profile for the same single component. Using this as input, a secondary NN was trained to map the hyper-resolution single component profile to 3D hyper-resolution data corresponding to the remaining two flow directions. Both networks were trained for 40 unique flow profiles. The networks were tested with the remaining unseen flow profiles and geometries with different inlet conditions for rigorous assessment of flow predictions.

Results: Our trained hyper-resolution network was able to successfully reconstruct high-resolution flow in the same direction as the 5% low-resolution data in geometries previously unseen by the NN. Further, the secondary network predicted the other two velocity components successfully. Comparison between the streamlines of the predicted hyper-resolution 3D profile with CFD ground truth show good agreement in the predicted patterns of the flow, as well as in its magnitude. Areas of recirculation near the inflow cannula were preserved in the hyper-resolution predictions, as well as areas of slow flow, which may be of interest when assessing thrombogenicity. Overall prediction time for our novel NN was less than 0.25 seconds for a 3D spatial resolution of up to 1 million datapoints per geometry.

Conclusion: Our hyper-resolution network resolves high-detail 3D LV flow patterns in less than half a second of prediction time, starting from low-density data such as ultrasound. As a result, a reconstruction of the 3D flow profile can be accurately produced for previously unseen geometries. This can introduce a paradigm shift for rapidly assessing LV hemodynamics for LVAD patients which is crucial for determining hemodynamics and thrombotic complication risk.

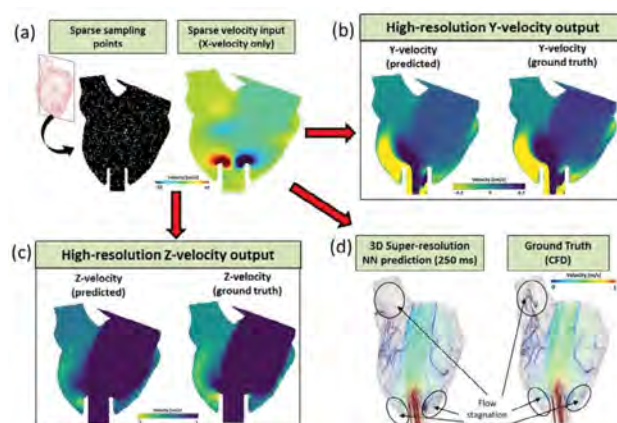


Figure 1. (a) schematic showing low-resolution and sparse input locations (left) and low-resolution sparse X-velocity input map (b) neural network output of hyper-resolution Y velocity for same spatial region (left) and ground truth CFD (right), (c) neural network output of hyper-resolution Z-velocity in same spatial region (left) and ground truth CFD (right), (d) neural network hyper-resolution 3D velocity profile and flow pattern prediction (left) compared to ground truth CFD (right) showing that the flow recirculation and stagnation zones are predicted accurately. Neural network predictions take approximately 0.25 seconds for full 3D predictions.

BIO28

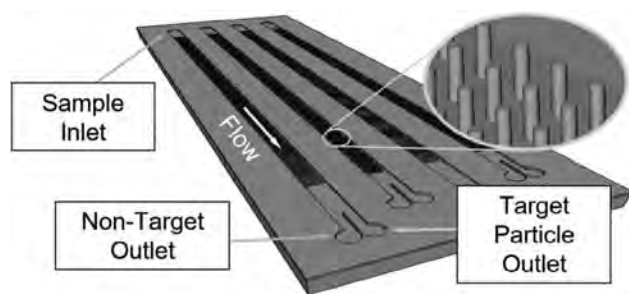
A Biologically Specific Cell Separation Device without Cell-bound Labels or Tags

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Precision cell based therapies, including emerging CAR-T and precision allogeneic stem cell transplant, require separation and collection of specific cells from a large volume of cells. Centrifugation based methods, fluorescence-activated cell sorting (FACS), and magnetic-activated cell sorting (MACS) are not sufficiently specific or require binding of labels on target cells necessitating subsequent label removal and addressing clinical safety concerns. A new biologically specific continuous flow separation technique with sufficient throughput is being developed to address this unmet need. The device incorporates microfluidic channels containing fields of functionalized obstacles or pillars and two effluent ports to carry the purified target and non-target cell solutions. Separation driven by transient cell-obstacle interactions differs for the target cells. Selected antibodies or ligands securely bound to the obstacle surfaces within the device alter the trajectories of the target cells producing a highly specific separation. The focus of this study was to evaluate bound antibody mediated cell-obstacle interactions and subsequent separation within a prototype device.

Methods: Microfluidic devices were designed utilizing computational fluid dynamic techniques and fabricated with soft lithography. Obstacles within the device were functionalized by adsorption of selected proteins (antibody/antigen). To minimize variability, a model system was employed consisting of functionalized and non-functionalized solutions of 10 μ m polystyrene microspheres. The antibody-antigen model was provided by a readily available goat anti-human IgG system. The interplay between fluid forces and antibody-antigen interactions as microspheres contacted and rolled around the obstacles was assessed over a range of flows. Video microscopy and particle tracking were used to quantify particle-obstacle interactions and effluent particle counts.

Results: Devices were successfully fabricated with 40 μ m high, 10 μ m diameter obstacles within a 750 μ m wide channel. Particle count analysis showed the ratio of particles exiting target effluent side to non-target effluent was 0.26 and 0.93 ($p < 0.001$, Fisher exact) for non-target and target particles respectively. Comparison of particle trajectories demonstrated the antibody-antigen mediated interactions altered the trajectories relative to the non-functionalized microspheres. Conclusion: This study demonstrates continuous flow separation can be mediated by transient antibody-antigen interactions. A device with surface bound antibodies or ligands that interact with native cell membrane proteins during transient obstacle-cell interactions holds promise for enabling a highly selective continuous flow separation without binding tags or labels to cells.



Device Illustration (Simplified)

BIO29

Novel Vertical Flow Immunoassay Design for the Multiplex Detection of Inflammatory Biomarkers

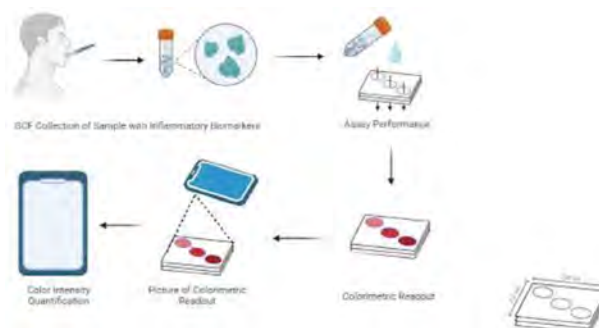
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Background: Inflammation is a central driver of chronic kidney and heart disease. Other than conventional blood-based lab tests, no rapid testing method exists to readily diagnose inflammation. Several inflammation biomarkers (MMP-9, IL-6, CRP) are present in gingival crevicular fluid (GCF) excreted from the periodontal pocket. As GCF provides a noninvasive alternative, we created an at-home test kit consisting of a paper microfluidic device capable of inflammatory biomarker detection along with a companion application for mobile phones to be used in the colorimetric readout of the microfluidic device. Here we test the ability of the microfluidic device to simultaneously detect different biomarkers and test the accuracy of the companion app to detect color change from the device.

Methods: A biomarker detection kit was designed to include: a paper-based vertical-flow immunoassay (VFIA) microfluidic device and companion application for colorimetric detection of immunoassay results. The VFIA was designed as a square, with 4 wax-printed circles on the inside of the square. Each circle contained immobilized antibodies for the detection of inflammatory biomarkers. The app was designed with a Python framework and KivyMD for the GUI to detect the presence of the desired biomarkers and securely store the information for the user to access. Using a color-detection algorithm, the application analyzed and categorized colorimetric readouts from the VFIA into high, medium, low intensities. The accuracy of the companion application compared detection values from colorimetric readouts to threshold values of high, medium, and low concentrations.

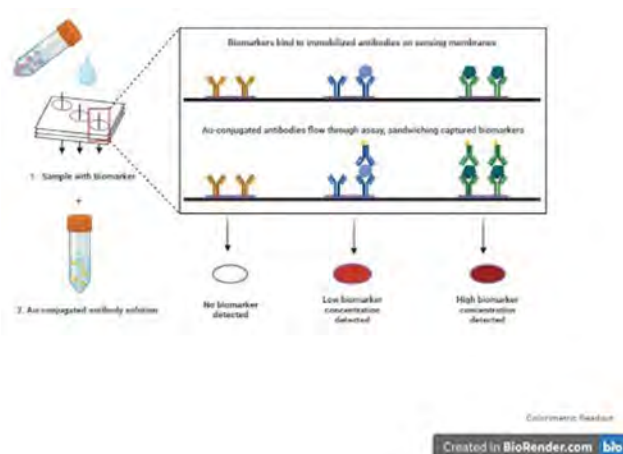
Results: The VFIA and companion application shows a high detection accuracy for inflammatory biomarkers (CRP, MMP-9, IL-6). Although ongoing work is currently being done to enhance the VFIA functionality and improved detection accuracy; we have goals for continual improvements for increased diagnostic sensitivity and specificity. Currently, our fully functioning app with a user friendly interface and intuitive instructions is capable of detecting concentrations with colorimetric readouts and providing results and suggested guidance to the user about their risk and severity of inflammation.

Conclusion: A biomarker detection kit has been designed to allow for a user-friendly, noninvasive, point-of-care diagnostic for the detection of inflammatory biomarkers associated with heart and kidney disease. Through verification and validation of the microfluidic device and the application, we have successfully demonstrated a high detection accuracy. Further work is underway to enhance the functionality of the microfluidic device for stronger antibody-biomarker conjugation. For the companion app, greater accuracy is needed to increase the sensitivity of the diagnostic device. Full development of this kit will provide a tool for early risk detection of biomarkers associated with heart and kidney disease.

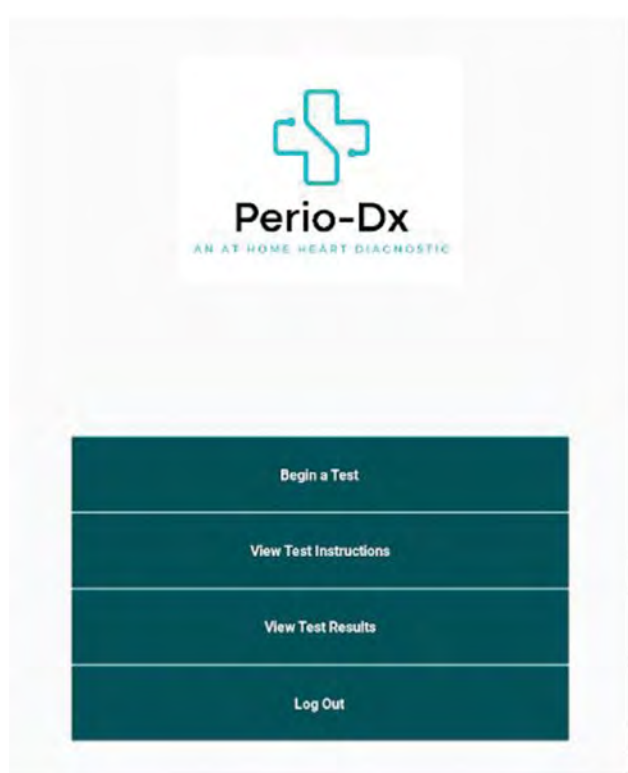


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Overview of the Biomarker Detection Process



Biomarker Detection Sandwiching Mechanism



Graphical User Interface Layout for the Companion Application

BIO30

Hyperthermic Extracorporeal Applied Tumor Therapy (HEATT®) for Unresponsive, Progressive Metastatic Prostate Cancer with Severe Bone Pain

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Background: Hyperthermic Extracorporeal Applied Tumor Therapy (HEATT®) is veno-venous perfusion-induced systemic hyperthermia with a heart-lung pump, dialysis, blood sorbent, and CO₂/pH control with flow at 20% of cardiac output to homogeneously increase core temperature to 42°C for 120 min while normalizing fluid and electrolyte changes. Two Phase 1 FDA trials (advanced lung, ovarian cancer), demonstrated safety and efficacy. HEATT® is well tolerated with no known long-term complications noted. A male with androgen-resistant Stage 4 prostate cancer with severe bone pain was treated with HEATT®, followed by six cycles of docetaxel. Four months post-treatment, the patient reported absent bone pain and normalization of prostate-specific antigen (PSA). **Methods:** Informed consent was obtained. Exclusion criteria included recent brain surgery, metastasis or stroke; organ failure; sepsis; or active bleeding. HEATT® uses femoral-jugular cannulas placed by image guidance in a veno-venous circuit (all individual components FDA approved). Upon general anesthesia and systemic anticoagulation, Interventional Radiology placed a triple lumen central line, arterial line, and right internal jugular (IJ) cannula (15Fr) with the tip at the cavo-atrial junction for infusion of heated blood and right femoral cannula (15 Fr) with the tip in the intravenous cannula (IVC) at L2 for drainage. The HEATT® cannula circuit flow was at 30% cardiac output to increase the core temperature to 42°C for 120 min. The patient was cooled to 38°C, and then recovered. **Results:** A 65-year-old male with a past medical history of hypertension/hyperlipidemia, type 2 diabetes, and stage 4 widely metastatic prostate was cancer treated with radiation and androgen deprivation therapy. Significant disease progression as evidenced by rising PSA, a bone scan showing extensive osseous metastatic disease, and severe bone pain. Pre-HEATT® PSA was 14.6. Following HEATT®, the patient completed six cycles of docetaxel. At the four-month follow-up, he reported no bone pain, PSA had reduced to 2.4, and a bone scan showed a reduction of uptake in the known lesions with no new metastatic lesions. **Conclusion:** Docetaxel therapy is considered successful if the PSA drops by 30%. Our patient showed an 85% reduction in PSA with elimination of bone pain, a reduction of present lesions, and no progression of disease on early follow-up. HEATT® may prove effective as a novel treatment modality for widely metastatic unresponsive prostate cancer or as an adjunct to standard therapies for a variety of unresponsive metastatic cancers.

BIO31

Host Response to Implantable Shape Memory Polymer Foams

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Background: Vascular occlusion devices have become more prominent over the past few decades to obstruct blood flow into damaged vessels. Implantable shape memory polymer foams were studied in multiple preclinical studies using various animal models. These studies focus on multiple applications; however, the basis of each device is to provide a scaffold for blood cells to get trapped in, thus expediting the clotting process. The Shape Memory Medical TrellixTM and IMPEDE Embolization PlugTM are two devices created using this technology. While multiple animal models have been used, a comprehensive summary of the healing response to implanted foams across animal models has not been performed.

Methods: To assess the effectiveness of the polymer foam devices across multiple animal models, a retrospective of previous animal studies was performed. Porcine and rabbit animal models were selected. In the porcine model, intravascular occlusion devices were studied within various vessels, and in the rabbit model, occlusion devices within aneurysms were studied. In each of these studies, the tissues were then evaluated histologically for the amount of degradation of the foams at various time points. Additionally, the host response was evaluated by analyzing the type/extent of cellular response within and around the scaffold device. This overall healing response was then compared across the different animal models.

Results: Results showed that the healing process for both animal models was consistent in that the devices in both the porcine and rabbit models healed from the outside inward— that is, the outer layer had more advanced healing, while the centers exhibited more immature healing. In both animal models, the healing also progressed as the implant duration increased. However, in rabbits, this healing progression seemed to occur faster when compared to the porcine model. Another notable difference in the animal models was the rate of degradation of the polymer foams: the foams degraded much faster in rabbits than in the porcine model. This is hypothesized to be due to inherent differences in the animal model (smaller size, faster metabolism, etc.).

Conclusion: Multiple animal models have been utilized in studying these types of implantable devices, and while there may be inherent differences, the overall healing response is consistent and favorable among the types of studies. These results underscore the potential clinical efficacy of implantable foam devices in promoting a consistent and controlled healing response. However, the question of how the device performs in humans has yet to be studied at a histologic level. With the Impede Embolization Plug being recently cleared for use by the FDA in 2018 due to the results of the preclinical studies performed, future work should aim to incorporate human results in a similar analysis to provide the most robust evaluation of these types of devices.

BIO32

Bio-Functionalized Micro-Trench Prosthetic Surface Supports Endothelial Retention & Anticoagulant Phenotype Under High Flow

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Background: Heart valve disease (HVD) is a global health concern, and synthetic prosthetic valves (PV) are the most viable option due to their superior durability, particularly in young adults. However, they present challenges such as hypercoagulation, inducing 6% annual cumulative rates of thrombosis/bleeding events. Endothelial cells (ECs), vital in the body's thrombosis management, have shown promise but face difficulties on mechanical implants due to rapid denudation caused by high shear stress. We hypothesize that novel shear-stress-reducing micro trench topography will create a functional endothelium on a synthetic PV surface by retaining ECs and providing an anti-thrombotic surface phenotype.

Methods: Micro-trench geometry 100um x 150um (width x depth) was manufactured on Ultrahigh Molecular Weight Polyethylene (UHMWPE) substrate. Porcine aortic valve endothelial cells were isolated and cultured for 5 - 7 days and seeded on the micro-trench substrates and controls (flat UHMWPE) for 24 hours to create a biohybridized surface. Post-seeding, we applied 100dyn/cm² bulk shear to the samples and controls using our novel, multifunctional bioreactor system that generates high shear for 48 hours and five days. Using the OpenFOAM Computational modeling tool, we determined the local shear range experienced by the cells. ECs' phenotype was analyzed via immunohistochemistry (ACTIN, VE-Cadherin, and eNOS), and nitrite concentration was quantified using Griess assay.

Results: The trench topography induced multiple microdomains with different shear levels, as determined by the simulation results, with the Base(B) ranging from 0 – 6 dyn/cm² and the Wall(W) ranging from 0 - 40 dyn/cm². The cells at W formed confluent monolayers with VE-Cadherin expression, and cell alignment was statistically different (p<0.0006) as the cells were more perpendicular oriented in comparison to B with sparse, circular, and spread cells (figure 1). This reveals a collective spatial organization of the cells within the same shear band. Although there was increased cell proliferation within the trench five days post-shear, there was no significant difference between EC alignment at day two vs day 5 (p>0.5). Figure 2 showed that the cells within the sheared trench expressed eNOS(an anticoagulant phenotype) mainly localized at W and had nitrite concentration more than 8-fold (p<0.0001) compared to static flat and static trench controls, thereby providing an anti-thrombogenic response for clot prevention.

Conclusion: Our study successfully demonstrated the creation of a biohybrid prosthetic surface that promotes endothelium formation in a relatively high-shear environment. The spatial orientation and collective remodeling of the ECs provide valuable insights for developing a stable biohybrid surface that paves the way for performance in diverse clinical settings and developing next-generation prosthetic valves.

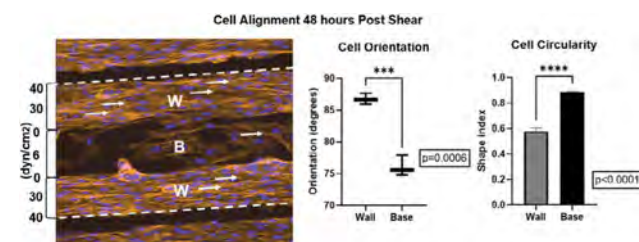


Figure 1. shows ECs alignment at the Wall(W) vs. Base(B) using ACTIN. ECs at W are aligned perpendicular to flow and more elongated than B post shear. Statistical significance is p<0.0006 and 0.0001, respectively. ACTIN(Yellow), DAPI (Blue).

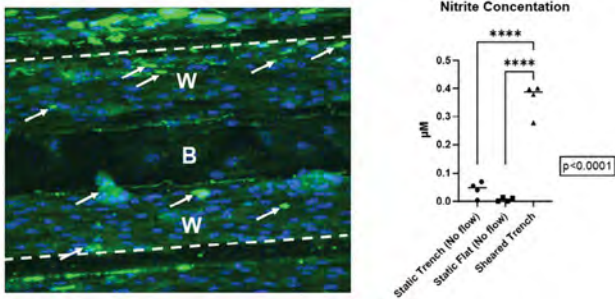


Figure 2. shows eNOS expression closer to the Wall(W) than at the Base(B) of the trench 24 hours after shear. Quantitative measurement reveals that the ECs within the trench produced a statistically significant nitrite concentration($p < 0.0001$) compared to the static (flat and trench) controls. Blue – DAPI, Green – eNOS.

BIO33

Computational Fluid Dynamics Optimization of Micropatterned Surfaces: Towards Biofunctionalization of Artificial Organs

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Background: The development of durable cardiovascular implants is limited by surface-induced thrombosis on synthetic biomaterials. Conversely, endothelial cells (ECs) lining the vasculature provide natural thrombo-resistance, hence long-term hemocompatibility. Unfortunately, the high levels of shear stress in most artificial organs prevent stable retention of ECs. Prior research has demonstrated a strategy of introducing deep grooves, or “microtrenches” in blood-wetted surfaces to locally attenuate the wall shear stress (WSS) to tolerable levels (10 to 50 dyn/cm²). Notably, the height of the micro patterns varies from a few microns to hundreds of microns across studies. This numerical study aimed to optimize the dimensions and the shape of microtrenches to maximize EC retention at 500 dyn/cm² WSS.

Methods: Parametric CFD optimization of height, width, and the gaps of the microtrenches was first conducted with CAESSES coupled with open-source software, OpenFOAM. The fluid was assumed Newtonian with a viscosity of 3.5 cPs. The independent variables were: depth, pitch, and draft angle of the microtrenches, and the objective function was the proportion of surface area within the upper and lower bounds of shear stress 10-50 dynes/cm².

Results: The baseline geometry (Figure 2 first column) with height and width of 0.1mm and 0.8 mm exhibits a 1.1% surface area at the bottom of the trench within the target range. Increasing the width results in a dramatic decrease in the coverage. The trenches with height and width of 0.125mm and 0.1mm resulted in 1.4% coverage. The second series, introducing draft to the trench walls, found that an angle of 90 degrees provided the optimum surface coverage (67%).

Conclusion: This study found that introducing a trapezoidal variation to the previously rectangular microtrenches significantly increased the percentage of surface area with favorable shear stress for endothelialization. This study also presents a framework for optimization of surface topography of synthetic biomaterials to maximize EC retention in the presence of high shear stress (e.g. 500 dyn/cm²) as found in prosthetic heart valves, blood cannula, and other artificial organs. It also set the foundation for future experiment validation and extension to more complex flow geometries.

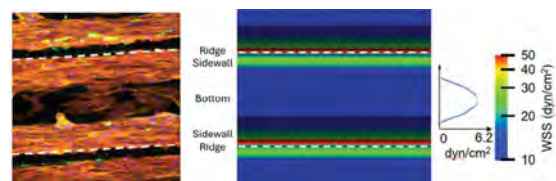


Figure 1. EC retention on the trapezoidal microtrenches compared to WSS profile.

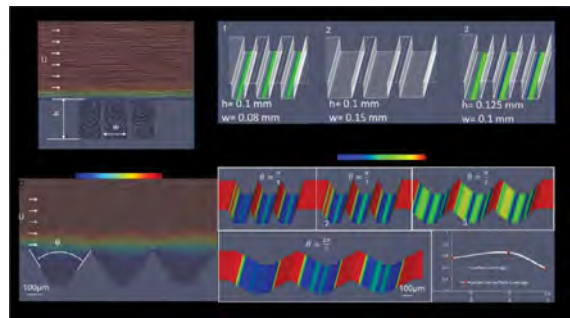


Figure 2. CFD guided shape optimization. (A) (C) Flow field on microtrenches at 500 dyn/cm² WSS. (B) optimization of h and w based on (A). (D) Interior angle (θ) optimization based on (C). The right corner is the surface coverage and projected surface coverage, for various θ .

BIO34

Hemocompatibility Evaluation of an Oxygenator with a Computationally Optimized Fluid Path in an Ovine Model for 48 Hours without Systemic Anticoagulation.

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Background: The Pulmonary Assist System (PAS) is currently under development as a wearable respiratory support system for patients with chronic lung disease. The PAS includes a low-resistance gas exchanger (PAS-GE) with a smaller surface area (0.9 m²) and a computationally optimized blood flow path to minimize recirculation. The system also incorporates an antifouling poly-carboxy betaine (PCB) surface coating designed to minimize protein and platelet adhesion in the circuit. In this study, we evaluated the hemocompatibility of the PAS-GE in a 48-hour ovine model with no systemic anticoagulation.

Methods: The PAS was attached to a normal sheep in a venovenous configuration using either uncoated (UC) or PCB-coated (PCB) PAS-GE. Each sheep was supported on the PAS for 48 hours with 2 L/min of blood flow and 4 L/min of oxygen sweep gas without maintenance anticoagulation. PAS-GE blood flow resistance was measured 5 minutes, 2 hours, 4 hours, and every 4 hours from the start support. The oxygen transfer of the device was measured at 5 minutes, 2 hours, 4 hours, 8 hours, and every 8 hours following the initiation of support. Animal hematology was measured at baseline and each of the above time points. Plasma-free hemoglobin (pHb), platelet count, and white blood cell count (WBC) were used as indicators of hemolysis, coagulation, and inflammation, respectively. After 48 hours of support, the clot weight in the device was measured after rinsing and drying the PAS-GE.

Results: A total of 5 experiments were performed with the UC (n=3) and PCB PAS-GE (n=2). The oxygen transfer was stable between baseline (UC: 78.3 ± 11.8 ml O₂/min, PCB: 83.9 ± 14.9 ml O₂/min) and endpoint (UC: 96.8 ± 19.9 ml O₂/min, PCB: 99.2 ± 5.2 ml O₂/min)(Figure 1A). The blood flow resistance of the UC and PCB PAS-GE did not vary appreciably from baseline (UC: 2.51 ± 0.71 mmHg/L/min, PCB: 2.42 ± 0.26 mmHg/L/min) over the study duration (Figure 1B). The baseline platelet count of the UC (178.8 ± 52.3 K/uL) and PCB (150.5 ± 43.13 K/uL) groups were comparable. However, the platelet count of the UC group dropped to 32.1 ± 9.5% of baseline after 8 hours and maintained this level to the end of the study (27.3 ± 13.4%). The PCB-coated PAS-GE preserved platelet count more effectively for the first 16 hours, but after 24 hours, the PCB group plate counts were similar to those of the UC group (Figure 1C). No indication of severe hemolysis or inflammation was observed due to the low, stable pHb (Figure 1D) or WBC. The clot weights of the UC and PCB PAS-GE groups were 68.7 ± 17.1 g and 48.4 ± 20.4 g, respectively.

Conclusion: These results demonstrate that the design of the PAS-GE allows it to function for 48 hours without any loss of function. The addition of the PCB coating appears to reduce platelet consumption and bulk clot formation, as indicated by the delay in platelet nadir and lower clot weight in these devices. Future work will also test a commercial oxygenator as a control.

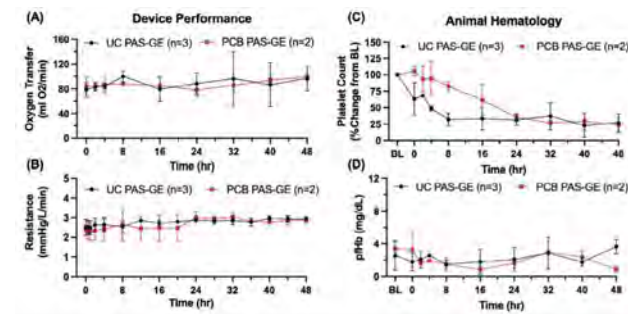


Figure 1. Summary of device performance, including (A) oxygen transfer and (B) blood flow resistance. Summary of animal hematology, including (C) platelet count normalized to the baseline value and (D) plasma-free hemoglobin.

BIO35

Quantification of swine immunoglobulin in human livers recovered on xenogeneic cross-circulation

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Background: The shortage of donor organs highlights a need for innovative approaches to organ recovery and rehabilitation. We have previously demonstrated that xenogeneic cross-circulation (XC) can support the functional rehabilitation of human donor livers declined for clinical transplantation, using a swine host as a bioreactor. However, exposure of the human liver to circulating swine blood and xenoantigens may prime the liver for immune-mediated complications upon transplant into a patient. In this study, we aim to characterize and quantify swine IgG and IgM deposition in human livers during XC to elucidate potential xeno-immunologic sequelae.

Methods: Human livers declined for transplantation were supported using a XC platform, as previously described. Livers were cannulated at the hepatic artery (HA), portal vein (PV), and inferior vena cava and connected to the swine host bioreactor via a veno-arteriovenous circuit (Figure 1). HA pressure approximated systemic pressure of the swine host, while PV pressure was maintained under 10 mm Hg. HA and PV flow were maintained > 0.2 L/min and > 0.5 L/min, respectively. Liver biopsies were obtained before XC, at 0, 12, and 18–24 hours of XC (n = 2 for pre XC and 0hr, n=3 for 12hr and 18–24hr). Immunohistochemistry (IHC) was performed on formalin-fixed paraffin-embedded tissue sections using goat anti-swine IgG and IgM antibodies, followed by staining with a biotinylated rabbit anti-goat antibody. The number of IgG and IgM positive cells were quantified using Nikon imaging analysis software. Student's t-test was used to perform pairwise comparisons and *p* < 0.05 was considered statistically significant.

Results: On qualitative analysis, swine IgG and IgM are observed to bind diffusely throughout the liver parenchyma immediately upon initiation of XC, and remain present through 24 hours of XC (Figure 2). Quantification of swine immunoglobulin demonstrates a significant increase in swine IgG within 12 hours (pre XC: 2 ± 2 cells/hpf, 12hr: 247 ± 74 cells/hpf, *p* = 0.03) (Figure 3a). Swine IgG deposition in human livers remained persistent after 18–24 hours of XC with no significant difference when compared to 12 hours (18–24hr: 143 ± 79 cells/hpf, *p* = 0.25). Swine IgM numerically increased during XC but was not statistically significant (pre XC: 33 ± 26 cells/hpf, 12hr: 139 ± 73 cells/hpf, *p* = 0.22) (Figure 3b).

Conclusions: This study demonstrates that swine immunoglobulins IgG and IgM rapidly deposit into human livers during organ rehabilitation using xenogeneic human-swine XC. Future studies will refine the XC platform to reduce swine IgG and IgM deposition, thereby minimizing cross-species immunologic reactivity for clinical translation of this bioengineering technology.

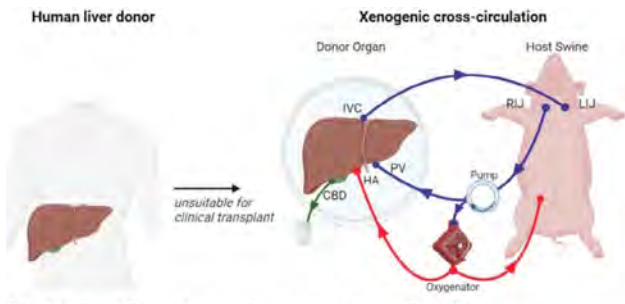


Figure 1. Overview of the human livers recovered on xenogeneic cross-circulation (XC).

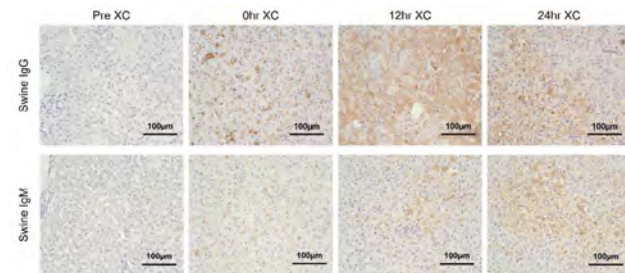


Figure 2. Diffuse deposition of swine IgG and IgM into human livers during XC were observed on immunohistochemistry.

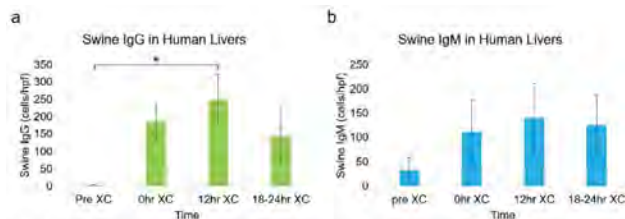


Figure 3. (a) Quantification of swine immunoglobulin demonstrated a significant increase in swine IgG within 12 hours (pre XC: 2 ± 2 cells/hpf, 12 hr XC: 247 ± 74 cells/hpf, * p = 0.03). (b) Swine IgM tended to increase during XC but was not statistically significant (pre XC: 33 ± 20 cells/hpf, 12 hr XC: 139 ± 73 cells/hpf, p = 0.22). All bar graph values represent mean ± SD.

BIO36

Design and Validation of a Wireless Focal 4-point Myocardium Bioimpedance Measurement System

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Background: Bioimpedance has been studied as a tool to detect heart transplant rejection and ischemia. However, previous studies have used global measurements, wherein readings of the entire heart and surrounding tissues can obscure true bioimpedance of the tissue of interest.

Methods: We designed a wireless bioimpedance measuring system and a 4-point suture-secured cardiac electrode patch. The system utilizing AD5940 impedance measurement IC was programmed to acquire 40-point impedance spectra on a log scale from 1 kHz to 195 kHz every 2 minutes. The measurement system and the electrode patch were tested using a non-survival ischemia pig model. The pigs were placed under general anesthesia and a sternotomy was performed. One electrode patch was placed in the heart's apex with another one proximally in the mid-septum. After baseline impedance measurements were procured, the LAD was occluded in a way that the ischemia affected the apex. The pigs were kept alive after infarction for 150 to 180 minutes. Complex impedance measurements (both amplitude and phase) were recorded in both locations until euthanasia. A total of 3 separate experiments were performed.

Results: The measurements in the 3.3-10 kHz frequency band showed consistent noticeable differences in bioimpedance between the apex and mid-septum 4-terminal recording patches in all 3 experiments. Additionally, we find that the phase component of complex bioimpedance is the most reliable indicator of ischemia, as shown in Figure 1. We performed a statistical analysis comparing bioimpedance phase evolution within the same electrode using frequency cuts at 3376.52, 5065.54 and 9959.1 Hz. For comparison within the same electrode, the phase readings were grouped in 4 bins: baseline measurements, 0-30, 30-60, and 60-90 minutes after LAD occlusion. An ANOVA test was performed for each electrode and frequency, which revealed significant difference in phase mean readings for all four bins. P values near 5 kHz can be seen in Table 1. **Conclusion:** Our wireless 4-point bioimpedance measurements show that localized lesions of the myocardium due to an infarct affecting the apex produces changes in the complex bioimpedance magnitude and phase. Our analysis of three separate experiments shows that the bioimpedance phase is a more robust and reliable measure of ischemia.

Myocardium Impedance Measurements Cut at 5065.54 Hz

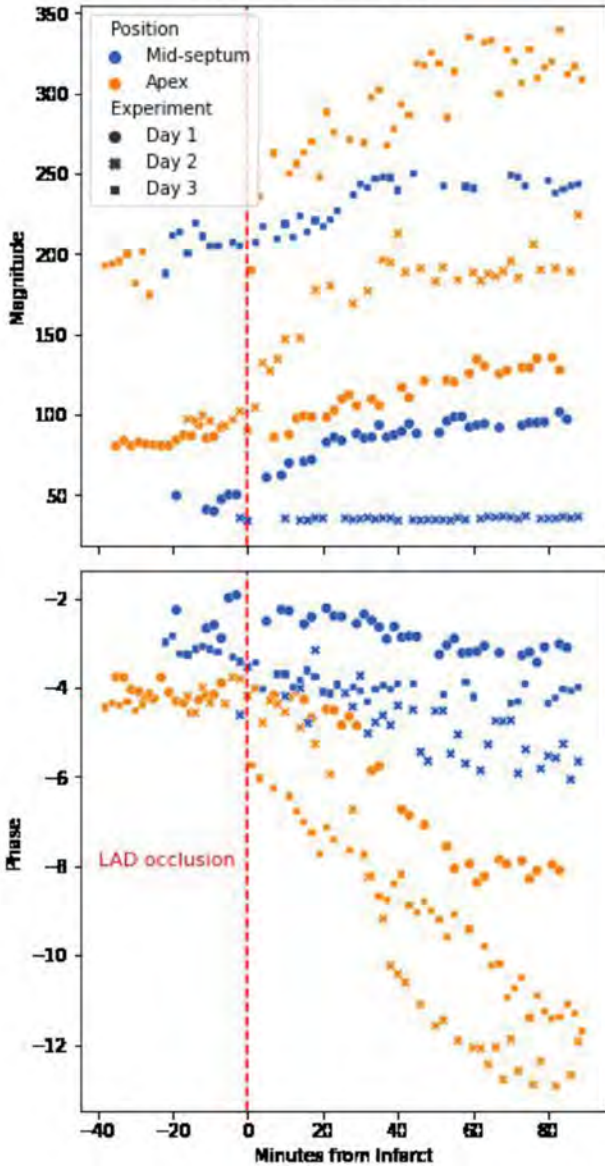


Figure 1. Impedance magnitude and phase at 5065.54 Hz

Table 1. ANOVA test results at 5065.54 Hz

Experiment	Electrode patch position	p value
Day 1	Mid-septum	1.05×10^{-7}
Day 1	Apex	9.36×10^{-24}
Day 2	Mid-septum	1.2×10^{-6}
Day 2	Apex	1.98×10^{-23}
Day 3	Mid-septum	1.33×10^{-13}
Day 3	Apex	1.47×10^{-27}

BIO37

3D Technology for surgical planification in a challenging case

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Introduction: Three-dimensional technology can be used as a complementary tool for surgical planification by providing a real and tangible exposure of the future surgical field.

We aim to present a challenging surgical case of an arteriovenous fistula at the aortic arch where this technology was used.

Case Presentation: A 38-year-old man hypertensive, Syrian refugee with previous history of being bombed with shrapnel impact to the upper thorax went for cardiac evaluation refereeing dyspnea on minimal exertion. Details of his previous hospitalization could not be obtained. The patient also referred increased collateral circulation of the thorax. After further evaluation, the patient was diagnosed with an arteriovenous fistula between the aortic arch and the innominate vein. The venous circulatory system was extremely developed.

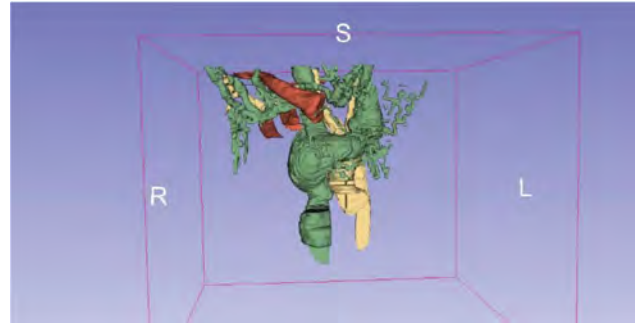
With this diagnosis the patient was accepted for surgical exclusion of the fistula. Interventional approach was rule out due to close relationship of the aortic orifice of the fistula, the left subclavian artery and the left coronary artery.

Due to the high anatomy complexity of the thorax, three 3D printing models were printed. Two anatomic model (FDM technology) were printed in order to study the relationship of the fistulous tract with the surrounding structures and the sternum. (Figure 1) The last model was printed using PolyJet technology and it was used for planning the closure of the fistula. The precise location of the fistula was observed. (Figure 2) As the vascular network was highly developed, a 3D virtual reconstruction was also done in order to identify the veins while performing the sternotomy, as well as the best approach to the right subclavian artery when cannulation. (Figure 3)

The surgery was performed under general anesthesia. The skin of the patient was marked in order to identify the bone aspects of the clavicle, the sternum, the ribs and the portion of the right subclavian artery that was most accessible for cannulation.

Cardiopulmonary bypass and core cooling was conducted with peripheral cannulation, before median sternotomy. After careful dissection of the great vessels, the patient was put under complete circulatory interruption with cerebral perfusion. The ascending aorta was incised longitudinal towards the arch. The fistulous orifice was identified and reassured with the model. It was closed with discontinued suture. When the patient was at temperature with good hemodynamic conditions the bypass was discontinued. Intraoperative transesophageal echocardiogram showed correct exclusion of the fistulous tract. The recovery went uneventful.

Conclusions: 3D technology (virtual and models) is a complementary tool that provides anatomic information in space and time, facilitating surgical planification to obtain successful results, avoiding potential complications.



BIO38

Characterization of Manufacturing Methods and Materials for Neurovascular Simulators

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Background: Synthetic neurovascular simulators based on newly available technologies are being developed for training, preoperative planning for applications like aneurysm and bypass surgery. Their physical realism, essential for their effectiveness, depends mainly on the manufacturing method and materials employed. Case-specific, hollow and elastic models have been presented in literature, but a comprehensive characterization and quantitative comparison of the materials and methods used is missing. We aimed at comparing different solutions for the production of neurovascular simulators to identify the optimal one in terms of physical realism.

Methods: Fourteen (n=14) materials commonly used in research and development of vascular phantoms have been included. They comprehended nine commercially available silicones with different hardnesses for casting and injection molding, one soft resin for stereolithography, two soft materials for polyjet printing and two silicones for fused deposition modeling. The mechanical tests were performed according to standards, and comprised hardness tests on scale Shore A and AO, uniaxial tensile tests and needle-puncturing tests. The results obtained have then been quantitatively compared with biological vessels.

Results: The tests revealed the manufacturing challenges and limits of casting and injection molding in reproducing reduced size samples. A sub-selection of materials presented properties similar to biological tissues: seven presented hardness shore A inferior to 10; six showed tensile strength between 1 MPa and 6 MPa and elongation at break between 60% and 290%; eleven materials resulted in an elastic modulus of 0.2 -3.5 MPa. Of the materials tested also with needle-puncturing, four presented a realistic needle insertion force of 1 - 10 N. Differences were also observed and quantified in the results of tension tests of 3D printed samples depending on the printing direction of the sample. The best neurovasculature mimicking material was the commercially available DragonSkin 10 fast (Smooth-On, Macungie, Pennsylvania, USA) for both stereolithography and fused deposition modeling, with hardness Shore A of 13.62 ± 0.57 , tensile strength 1.07 ± 0.04 MPa, elongation at break $221.39 \pm 10.99\%$, elastic modulus 221.39 ± 10.99 MPa and needle-puncturing force of 14.70 ± 1.81 N.

Conclusions: Several materials exhibited characteristics of elasticity and softness that were suitable, making them potential candidates for replicating the properties of neurovascular tissues. Prospectively, employing silicones with additive manufacturing holds great potential.

BIO39

Experimental and Numerical Analysis of the Particle Migration in Gap-like Flows of Ventricular Assist Devices

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Background: Patients with advanced terminal heart failure require a donor heart or a technical solution of a ventricular assist device (VAD). A VAD pumps blood from the left ventricle into the artery. To generate the required pressure, the impeller rotates at several thousand revolutions per minute. These high rotational speeds and speed gradients affect the blood. Blood consists of a low-viscosity plasma and high-viscosity cellular components. To minimise damage or activation of the blood components, it is important to numerically identify areas of high stress in a VAD (e.g. bearing regions or side chamber of radial impellers). In these simulations, a single-phase blood analog fluid is used, which has a similar density and viscosity as blood. Nevertheless, this assumption can lead to a deviation, especially in narrow gaps. It is known that in gaps between 7-300µm, the particles migrate to the center of the vessel, and a low-density layer of plasma forms between the wall and the cells. It is known in medicine as the cell-free layer (CFL). After the successful optical analysis of the particle migration, the influence of particle migration in a stationary channel under the flow conditions of a VAD gap ($Re \sim 100$; 150µm) was investigated both experimentally and numerically.

Methods: To better understand the flow in narrow gaps, these flow conditions were adapted to a stationary narrow gap-like flow of ventricular assist devices. Optical analysis, wall shear stress, and pressure measurements were used to study particle migration and flow behavior in these confined spaces. Various Reynolds numbers were tested (50-150), which represent typical flow conditions that prevail in VAD gaps. Various blood with different hematocrits and blood analog fluids were used. In addition, a numerical model was developed based on the optical measurement and particle distribution over the channel height. This takes into account the effect of cell migration based on the change in viscosity over the height of the channel.

Results: A cell-free layer was found in all tested particulate fluids, leading to a reduction in stress and pressure loss compared to single-phase fluid without a cell-free layer. The numerical results were compared with the previously measured experimental results with particle-laden blood analog fluids and with newly recorded blood measurements with particle volume fractions up to 5% ($Re = 50$ to 150). A good agreement was found between the numerical simulations and the experiments on wall shear stress and pressure losses. Furthermore, it can be seen that the shear stress in the fluid decreases as well.

Conclusions: The results in our experimental setup led to the hypothesis that the CFL-formation and stress reduction are also present in the narrow gaps of VADs. A satisfactory level of agreement was attained between the experimental observations and the numerical results. Now it is possible to predict numerically the impact of particle migration on the flow.

RENAL1

WATER-SAFE: A Low-Cost Microplastic Detection System for Environmental and Human Health

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Background: Humanity is bombarded by microplastics on a daily basis. On average, adults consume up to 52,000 microplastic particles (MPP) every year, or 142 every day. Over time, consumption of MPP causes major health problems including altered metabolism, neurotoxicity, reproductive and developmental defects, and increased risk of cancer. This is a burden on individuals as well as the healthcare infrastructure as a whole. To mitigate this, we are focusing on a method to inform the level of MPP they are consuming through drinking water by creating a device that analyzes the concentration and the size distribution of 10 of the most common MPP in a water sample. Traditional laboratory grade methods of microplastic detection require tedious hands on operation and use expensive equipment often totaling over \$20k. Our semi-automatic prototype device not only requires minimal operation from the user but is also expected to cost under \$3000. Ultimately we are developing a low-cost device which simplifies the process of identifying MPP in drinking water, arming property owners and homeowners with the proper tools to protect their health and pursue safe water sources.

Methods: Fine retention filters were used to concentrate MPP contaminants for imaging from samples 1L in volume. A monochrome microscopic camera was then utilized for image capturing, illuminated by a ring of 460 nm and 525 nm LEDs, causing varying sample fluorescence. The assembly consists of interchangeable 495 nm and 590 nm longpass filters to block out illuminating light and aid in image contrast/particle detection. For image analysis, an ImageJ based algorithm utilizing ferret sizing was created, which outputted both size distribution and concentration. Dynamic and static thresholding was performed against a range of size constraints in order to maximize the accuracy as determined by percent difference.

Results: Initial results show that the device is able to detect particles smaller than 10 μm – 7x smaller than a human hair. We tested 11 MPP for fluorescence at 590 nm, 10 of which showed prominent excitation, providing increased contrast for the detection of microplastics. The algorithm testing proved successful as it accurately identified and counted MPP in the obtained images, discerning them from known contaminants as calcium.

Conclusion: Already the device is able to effectively detect, count, and measure the size of the most common types of microplastic found in the environment, which is incredibly promising for the use case of our device. In further development of the project, the device will capture sample images with pre-identified contaminant concentrations which will be used as parameters in the algorithm training. Verification procedures will be conducted by analyzing samples with pre-identified contaminant concentrations using the assembled device to verify desired 95% accuracy in MPP identification, counting, and size distribution analysis.

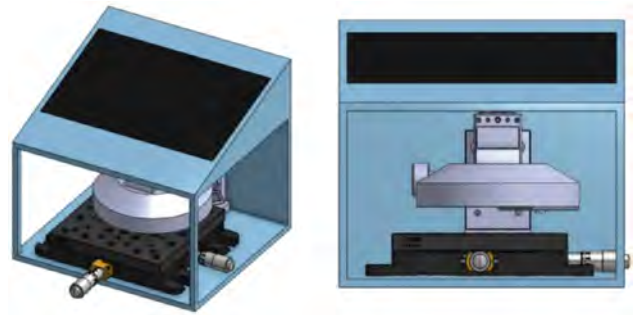


Fig. 1. WATER-SAFE device.

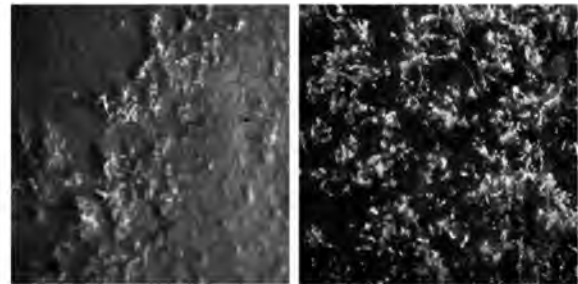


Fig. 2. PET microplastic particles imaged without fluorescence (left) and with fluorescence (right).

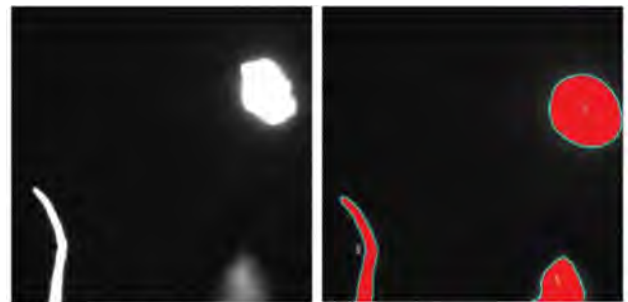


Fig. 3. Microplastic particles identified and highlighted by the algorithm.

RENAL2

Implantable Bioartificial Kidney Components in Ovine Model

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Background: In the United States, over 90,000 patients are waiting to receive a kidney transplant. Patients can survive without a transplant because renal function can be partially replaced by dialysis; however, dialysis is time consuming, costly for society, and allow toxic metabolites to accumulate. The implantable bioartificial kidney (iBAK) presents a promising therapeutic alternative for kidney disease, providing continuous filtration and alleviating the societal costs of dialysis. In the iBAK, human renal tubular cells are housed within a non-immunogenic and anti-thrombotic synthetic housing containing silicon nanopore membranes that mimic native renal filtration. Prototype iBAK devices have been tested in swine to confirm feasibility of operation. Here, we assessed the short-term safety profile of the iBAK device components in a healthy ovine model, which offers several advantages, including easier post-surgical management, and similar anatomic and coagulation profiles to humans.

Methods: A single-channel prototype iBAK filter was surgically implanted into a Suffolk sheep (female, 14 months, 47kg) under general anesthesia. The iBAK was placed in the animal's right iliac fossa using polytetrafluoroethylene (PTFE) vascular grafts to connect the inflow and outflow tracts of the device with the external iliac artery and vein respectively. Intraoperative IV heparin was used to prevent thrombosis during implantation. Postoperatively, the sheep received daily antiplatelet (Aspirin, 162.5 mg daily) therapy.

Results: After 7 days, fluoroscopy confirmed patency of the device and vasculature. Robust laminar flow in inflow, outflow, and intra-device channels was observed before explantation of the device. Grossly, the explanted device was without clot.

Conclusion: This model was chosen because of simplified animal management and post-operative care for long-term studies, and similar anatomic and coagulation profile to humans. This study serves as a foundational pilot study for further long-term safety profiling of the iBAK in an ovine model that will in turn allow studies in humans. Moving forward, we will use this evidence to increase the duration of testing to a 90-day period and begin to test the filtration capacity of this device. This study marks the first implementation of iBAK device components in an ovine model in a survival study.

The iBAK has potential to have a positive individual and societal impact for patients with end-stage kidney disease. Thorough testing in animal models is required prior to clinical studies in humans. This study demonstrates the short-term safety of iBAK component implantation in the ovine model which was successfully implanted and demonstrated no signs of thrombosis after a 7-day period without postoperative systemic anticoagulation beyond antiplatelet therapy. We will use this experience to plan long-term survival studies in sheep, for both safety and functionality testing and allow for graduation to clinical studies.

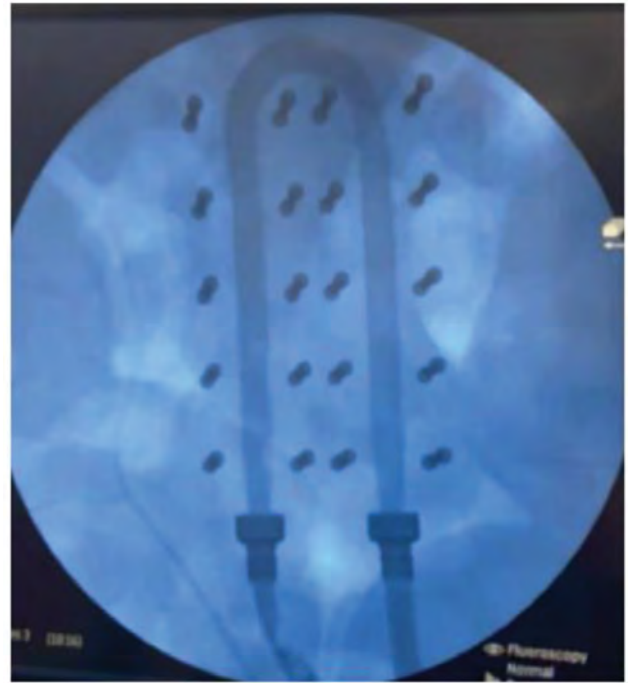


Image of fluoroscopy demonstrating flow through the device

RENAL3

Non-invasive Assessment of Urinary Glycolysis and TCA Cycle Metabolites Differentiate Improving vs. Worsening Kidney Function After Left Ventricular Assist Device Implantation

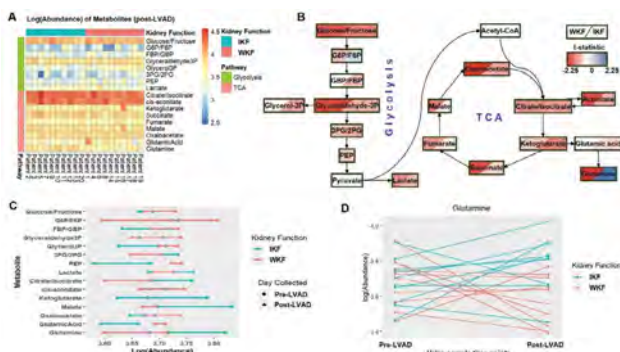
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Background: Metabolomic approaches are promising in nephrology research due to the impact of kidney function on urinary metabolite levels and the potential functional roles of metabolites in kidney complications. Our study aims to analyze the longitudinal changes in kidney metabolism in heart failure patients undergoing left ventricular assist device (LVAD) implantation by assessing glycolysis and tricarboxylic acid (TCA) cycle metabolites in the urine.

Methods: From an existing cohort of individuals undergoing LVAD implantation, we identified 10 individuals with improving kidney function (IKF) (median eGFR increase 66 to 100) and 10 individuals with worsening kidney function (WKF) (median eGFR decline 68 to 45) after 7 days following LVAD implantation. Liquid chromatography-mass spectrometry (LC-MS) measured glycolytic and TCA metabolites in urine before (day 0: pre-LVAD) and after implantation (day 7: post-LVAD). Targeted profiling of 17 metabolites from glycolysis and TCA cycle pathways was performed in urine samples. After median normalization and log transformation, we compared longitudinal differences in metabolites between IKF and WKF groups following LVAD implantation using permutation tests with false detection rate correction.

Results: TCA metabolites were generally more abundant than glycolytic ones, and the most abundant metabolite was citrate/isocitrate (Fig.A). Most of the metabolites trended toward a decrease in abundance from pre-LVAD day 0 to post-LVAD day 7 (Fig.B,C). Only glucose-6-phosphate/fructose-6-phosphate and glutamine had a higher mean abundance on day 7 compared to day 0, primarily in the IKF group. On day 7, the metabolite with the largest difference between the IKF and WKF groups was glutamine. The IKF group showed substantially higher glutamine levels than the WKF group on day 7 (Fig.D).

Conclusions: We found that longitudinal levels of glutamine (an important modulator of oxidative stress and apoptosis in renal tubular epithelial cells) differ substantially between those with improving kidney function and worsening kidney function after LVAD implantation. Studying the metabolic changes that occur in the kidneys in heart failure patients after LVAD implantation can offer valuable insights into the impact of LVADs on kidney health.



RENAL4

Anti-clogging Effect of Continuous Hemodiafiltration with Blood Recirculation

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Continuous renal replacement therapy is advantageous for patients with unstable hemodynamics because it gradually removes fluid and solute without altering the fluid levels or distribution. In pediatric dialysis, low flow from the body is required, but greater flow is needed to prevent clogging. As a solution, we developed a new continuous hemodiafiltration system with blood recirculation (CHDF-R), which enables separate settings for blood flow from the body and to the hemofilter. We compared CHDF-R with conventional continuous hemodiafiltration (CHDF) of bovine plasma and blood by monitoring the transmembrane pressure (TMP) and observing the hemofilter membrane surface. The flow rates of bovine plasma and blood were set at 30 mL/min. The blood recirculation flow rate was set at 170 mL/min, which achieved a rate of 200 mL/min to the hemofilter. TMP was recorded and 10-mL blood samples were collected 10 min, 1 h, 2 h, 3 h and 4 h after starting hemodiafiltration. Four hemodiafiltration trials were performed using CHDF and CHDF-R. A scanning electron microscope was used to examine the surface of the hemofilter membranes after hemodiafiltration with bovine plasma. When using bovine plasma, the postdialysis TMP with CHDF-R was significantly lower than with CHDF (median CHDF: 23.7 mmHg; median CHDF-R: 18.1 mmHg; $p = 0.029$). Likewise, when using bovine blood, the postdialysis TMP was also significantly lower with CHDF-R than with CHDF (median CHDF: 150 mmHg; median CHDF-R: 100 mmHg; $p = 0.029$). Macroscopic views of the hemofilter membrane after the tests using bovine blood showed significantly less deposition due to thrombosis after CHDF-R than with CHDF ($p = 0.009$). Similarly, electron microscopic analysis of the internal surface showed that more substance was present on the internal surface of the hollow fiber after CHDF than after CHDF-R ($p = 0.004$). The higher blood flow rate to the hemofilter would increase shear stress and prevent the accumulation of solutes on the membrane, thereby reducing the TMP. Coagulation within the two circuits was compared by measuring D-dimer, TAT and PIC levels. D-dimer levels did not significantly differ between the two circuits (median CHDF: 0.555; median CHDF-R: 0.515; $p = 0.081$), and all TAT and PIC levels were below the detection limits of 1.0 ng/mL and 0.5 mg/mL, respectively. The higher flow rate during CHDF-R did not appear to affect the coagulation pathway. To assess hemolysis, we compared the 4-h levels of Hb, lactate dehydrogenase, and total bilirubin for CHDF and CHDF-R. None of these three indicators significantly differed between the two circuits. Neither the higher flow to the hemofilter nor the blood recirculation appeared to cause hemolysis. CHDF-R appears to suppress accumulation of clogging substances by producing higher shear stress within hollow fiber membranes, leading long-term operation.

RENAL5

Ex-Vivo Evaluation of Fluid Removal Using a Hemodialysis System, xKideny.

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Background: There has been a global increase in the number of people suffering from renal failure. For patients with chronic kidney disease and renal failure, fluid overload is a major problem. To address this issue, Exorenal Inc. has developed a new hemodialysis system named xKideny. This system uses Active Pump Balancing (APB) technology and is significantly smaller than other home-use hemodialysis system available in the market.

This study focuses on evaluating the flow removal accuracy of the xKideny system. The assessment adheres to international technical standards established by IEC 60601-2-16, ensuring that the machine meets and exceeds the necessary benchmarks.

Method: The study utilized ultrafiltration methods to evaluate the accuracy of fluid removal during hemodialysis. The experimental medium was fresh bovine blood, and fluid control was achieved through the use of APB pumping technology by xKideny. The APB technology's usage of fluid pumping and balancing ensured precise management of fluid volume. xKideny measured and compared extracted fluid volumes with predetermined targets, demonstrating its precision in fluid removal. This is important in treating fluid overload in renal conditions. The experiments aimed to remove a specific amount of total UF over four hours.

Results: The prescribed volume of fluid removal varied between 2,340g to 2,730g for four hours. The balancing error amount during the entire treatment ranged from - 52.09g to 39.01g. The mean error was -0.75g/h with a standard deviation of 8.95g/h and an average balancing error of 1.009%.

Conclusion: The findings of this study reveal that the xKideny system effectively maintains fluid levels within the permissible range. The data provided in the study show that xKideny outperforms other home-use hemodialysis systems in managing fluid levels.

RENAL6

P-DxTM A Point of Care Phosphorous Diagnostic System for Chronic Kidney Disease Patient Safety

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Background: Advanced and End-Stage Renal disease (ESRD) or chronic kidney disease (CKD) pose the threat of reduced kidney function and regulation of Phosphorus (P), which in excess concentration can lead to muscle cramps or spasms, bone fragility/weakness, and in severe excess altered mental status, delirium, seizures, coma and death. One in 7 US adults are expected to develop CKD. Currently, no methods are available for at home patient tracking of P consumption; consequently, our team has developed a point of care (POC) analytic system to address these needs with a user-friendly app consisting of image recognition and volume estimation of a variety of foods and fluids, and a detection probe for the indirect and direct estimation of P content in these items.

Methods: The P-Dx system comprises three subsystems: 1. Imaging system- with a high-resolution camera and computational system. 2. Sensing- A probe system with a P specific probe and homogenizer for testing.

3. Software system with a graphical user interface (GUI) integrating machine learning.

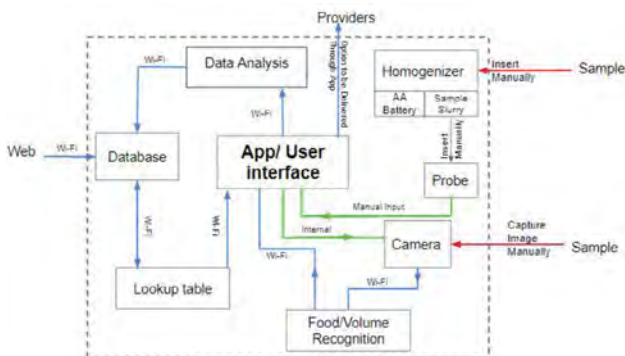
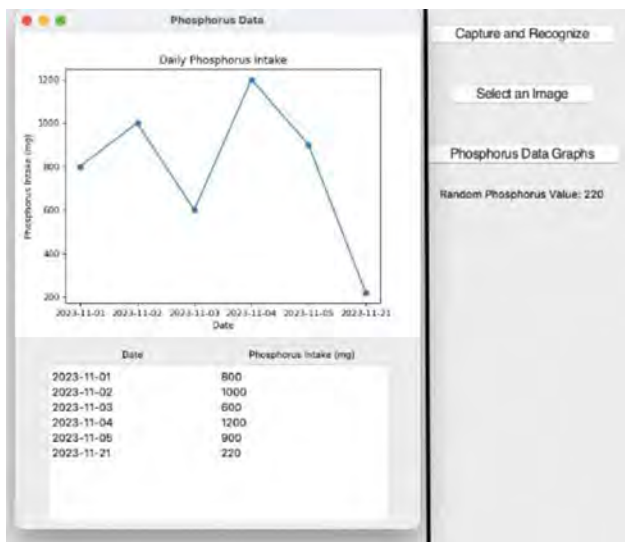
(GUI) – for volume and P estimation and concentration determination for given food or fluid; integrating smart machine learning for enhanced accuracy with continued use; USB or wifi capabilities. Samples of food and defined concentration P solutions were utilized for initial system testing.

Results: The ongoing development of this system aims to create valuable tools that improve End-Stage (ESRD) patient safety by addressing concerns related to phosphorus intake during eating/drinking. This will be done by utilizing a homogenizer to generate accurate representations of food samples that can be measured with an accurate phosphorus probe. Estimation will be conducted through a user-friendly app that can recognize food samples, determine their volume and further translate this information into P content with 85% accuracy. Lastly the user interface will also be responsible for generating daily and monthly intake values tailored to specific users, warning when they are nearing critical P intake values.

Conclusion: The global market size for Kidney disease is valued at 82 trillion dollars, and our team's system would offer an effective, non-invasive, at-home strategy for renal patients to monitor and track their Phosphorus consumption. With the success of creating and constructing this system, its accessibility may be extended in future development to present the opportunity to deliver a point of care diagnostic system for at-risk patients that are unable to access or visit in person health care facilities.



Figure 1: Homogenizer and Probe Housing



RENAL7

Implantable Hemofiltration Device for Hybrid Renal Replacement Therapy

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Background: Current dialysis patients face a demanding schedule with thrice-weekly, four-hour-long dialysis sessions, high/low blood pressure before/during the treatment, and strict restrictions on water intake. Although there have been studies on artificial kidneys that aim to completely replicate kidney function, both filtering 200 L of fluid a day and tubular reabsorption are extremely challenging to replicate artificially. Our group proposes a hybrid renal replacement therapy, in which an implantable hemofiltration device continuously removes an adequate amount of fluid from the blood, while the excessive waste products are concurrently removed through conventional dialysis treatment. Consequently, the body fluid volume is maintained, allowing patients to intake the same amount of water as the filtrate (we have designed it to be 1.5 L per day). The frequency of dialysis treatment can be reduced, which depends on the residual kidney function. This not only significantly improves the quality of life for patients but also yields favorable medical outcomes, attributed to the constant body fluid volume and blood pressure.

We have designed a hemofiltration device capable of operating under blood pressure without the need for an external pump, with a specific focus on preventing back filtration (See Figure 1). Short-term *ex vivo* experiments for 2 h utilizing goats under anesthesia have been designed to verify the device concept.

Methods: The hemofiltration device is a layered filter comprising a polyethersulfone (PES) dialysis membrane and micro-sized blood flow and filtrate flow channels arranged alternately. To prevent back filtration due to oncotic pressure, the filtrate flow channels are designed to be half the length of the blood flow channels and are positioned where the blood pressure exceeds the oncotic pressure. The device is connected to the carotid artery and vein of a goat with artificial vessels, and the goat is treated with heparin to adjust the activated clotting time to around 200 during the experiments.

Results: After connecting the device to the carotid artery and vein of the goat (see Figure 2), filtrate was successfully obtained. However, a decline in the filtrate amount was observed after 2 h due to blood coagulation. Modification of coagulation control is necessary, considering adjustments to both medication and dosage.

Conclusions: We have designed and fabricated the hemofiltration device for the hybrid renal replacement therapy. Animal experiments with goats are designed including the surgical procedure and anticoagulation control.

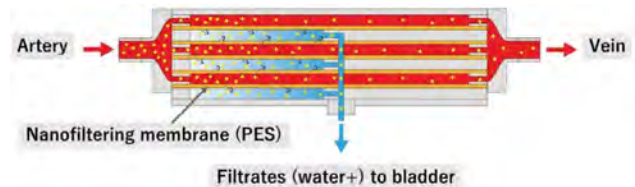


Figure 2. Photo of the ex vivo experiment.



Figure 1(a). Device design.



Figure 1(b). Photo of the manufactured device.

RENAL8

Incidence of Kidney after Heart Transplantation in patients bridged to transplant with Impella 5.5

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Background: Temporary mechanical circulatory support (tMCS) has been previously studied as an effective therapy in improving renal function in patients presenting with cardiogenic shock prior to transplantation. We present short-term and long-term renal outcomes in our end-stage heart failure population awaiting heart transplantation supported by tMCS.

Methods: We performed a single-center retrospective study on all patients bridged to transplant between April 2020 and August 2023. Patients who received a heart-kidney transplant, obtained a baseline glomerular filtration rate (GFR) above 60, or received extra-corporeal membrane oxygenation support were excluded. Baseline GFR was obtained the morning of device implantation and post-Impella GFR was recorded the morning of heart transplantation.

Results: During our review period, 36 patients underwent heart transplantation with the support of Impella 5.5, of which the median age was 61.5 (54-66). 16% were females and 44% were African American. 72% presented with non-ischemic cardiomyopathy. The baseline left ejection fraction was 19% (15-25.25). The median duration of support was 22.5 days (10.75-30.5). The baseline GFR was 45 ml/min (37.25-51) improving to 56 ml/min (43.75-66.5) after Impella 5.5, $p < .001$. The median duration follow-up was 519 days (197.5-943.5) with zero kidney transplantations and a 97% survival rate.

Conclusion: The Impella 5.5 holds the potential to improve short-term renal function in heart failure patients awaiting heart transplantation. The long-term effects of renal recovery correlated with Impella 5.5 placement mitigate the need for renal replacement therapies or dual-organ transplantation.

RENAL9

ADVANCE Kidney Health: Student, Faculty and University Engagement to Advance the Renal Workforce and Drive Innovation for the Future

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Background: Kidney Disease (KD) is a significant cause of morbidity and morbidity on the rise in the U.S. and worldwide. A widening gap is developing between the present workforce and technology available to address KD and that which is anticipated as needed to meet future demands associated with rising KD prevalence. We developed a program - ADVANCE Kidney Health (Arizona Technology Development and Clinical Education Program for Students in Kidney Health), aimed specifically at undergraduates, to foster interest, education, engagement and research in Kidney Medicine. The program is supported by the NIH. We report on the interim phase of this program.

Methods: A hands-on program was developed based on four pillars: 1) science, medical and engineering education; 2) training in innovation, entrepreneurship and translation; 3) experiential learning, mentorship and clinical immersion; and 4) needs-based application and practical translation – aimed at producing motivated, trained and committed biomedical trainees interested in renal health and science. Undergraduate students were recruited as Freshman/Sophomores immersed in didactic and lab experiences, advanced in Junior year with increasing lab and clinical exposure and specific project definition, culminating in a full Senior Year Engineering Design Capstone project. Students were selected by a faculty panel based on interest, academic performance, and diversity considerations. Students were required to report and present on results and participate in science/medical meetings fostering increasing engagement in the field.

Results: The program overall has attracted great undergraduate interest with increasing application rates, demand and popularity among engineering, physiology and computer science majors. In Year 1 of the program 80+ students applied with 4 students selected. In Year 2 100+ students applied with 7 selected. In Year 3 120+ students applied with 8 selected. All students have largely continued in the program with minimal attrition, in fact attracting more adjunct students to join through related elective courses available. In Yr 1, 3 Sr. design projects advanced; in Yr 2, 3 Sr. Design projects advanced, in Yr 3, 5 Sr. Design projects advanced involving 15, 15 and 26 students, respectively. In Yr 2 individual research was submitted to national meetings including ASAIO. In Yr 3 individual research was submitted to national meetings including ASAIO and BMES.

Conclusion: A multi-component engagement program aimed at undergraduates is an effective means of immersing students in the broad space of Kidney Medicine. It is apparent that students from a wide range of undergraduate majors find interest and a surprising “fit” into this space. A wide range of novel technologies and projects have emerged. Many have expressed interest in advancing to either medical school, graduate education or work in the kidney space. This approach to advance workforce development shows great promise for the future.

CARD1

Proteomic Profiling of Urinary Small Extracellular Vesicles to Predict Infections after Left Ventricular Assist Device Implantation

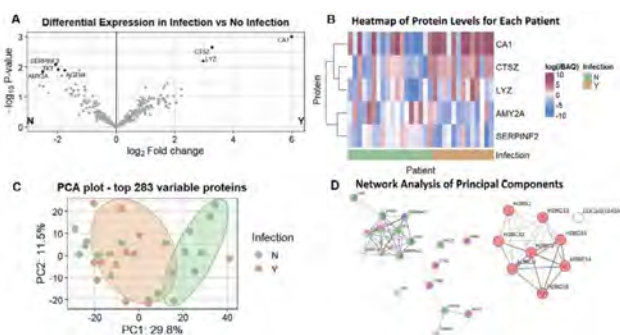
Adel M. Hassan¹, Samuel J. Shenoi¹, Shiyi Li¹, Katherine Nordick¹, Ivan Murrieta-Alvarez¹, Carl Walther¹, Camila Hochman-Mendez², Alexis Shafii¹, Kenneth Liao¹, Nandan Kumar Mondal¹; ¹Department of Surgery, Baylor College of Medicine, Houston, Texas, United States, ²Regenerative Medicine Research, Texas Heart Institute, Houston, Texas, United States

Background: LVAD-related infection continues to be a major obstacle to its widespread use to treat end-stage congestive heart failure. If there were biomarkers that could identify the patients at the highest risk for infection after LVAD implantation, it could open the door for targeted prophylaxis. Urinary extracellular vesicles (uEVs) are packed with potential proteome markers that could be associated with infection. Our goal was to identify post-LVAD implantation changes in the proteome of uEVs that were correlated with the development of infection later on.

Methods: We studied 31 LVAD patients by analyzing their uEVs untargeted proteomics using liquid chromatography with tandem mass spectrometry (LC-MS/MS) and intensity-based absolute quantitation (iBAQ) immediately before and one week after LVAD implantation. Over one year of follow-up, 13 patients developed confirmed, culture-positive infections. uEVs from both the infection (n=13) and no infection (n=18) groups underwent analysis for differential enrichment of proteins, followed by principal component analysis (PCA) and network analysis.

Results: We identified 7816 unique proteins, of which 283 were identified consistently across patients. Several biomarkers were identified as potential predictors of infection, including carbonic anhydrase 1 (CA1), which is involved in interleukin-12 signaling (p=0.001); cathepsin Z (CTSZ), which is involved in neutrophil degranulation (p=0.002); lysozyme (LYZ), which acts as a bacteriolytic (p=0.007); and the serine protease inhibitor SERPINF2, which promotes coagulation (p=0.008) (Fig. A). CA1, CTSZ, and LYZ were all upregulated in patients with infection, and SERPINF2 was downregulated in patients with infection (Fig. A,B). Only CA1 was different between the two groups pre-operatively (p=0.041). PCA revealed that 29.8% of the variation in iBAQ values was accounted for by a group of proteins involved in proteolysis, coagulation, the acute-phase response, and the general response to stress (Fig. C,D). CA1 was strongly correlated with this first principal component (r=-0.91). The second principal component explained 11.5% of the variation in iBAQ values, and this was a group of histone proteins (Fig. C,D). The infection and no infection groups largely separated along the first principal component, and a simple cutoff could be drawn with 92% sensitivity (12/13) and 56% specificity (10/18) for retrospectively predicting infection (Fig. C).

Conclusions: We found that certain urine biomarkers, including CA1, CTSZ, LYZ, and SERPINF2, are associated with an increased risk of infection in patients who have undergone LVAD implantation. Future prospective studies with larger sample sizes are needed to validate these findings and establish a more accurate prediction of infection risk in patients with LVAD support.



CARD2

MCS Shear Stress Promotes Downregulation of Key Platelet Adhesion Receptors via Shedding and Microvesiculation: Underappreciated Contributors to Device-Related Bleeding Coagulopathy

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Background: Platelet adhesion to damaged vessel walls and aggregation to one another are mediated by various adhesion receptors highly expressed on platelet membrane. Exposure to hypershear stress generated by mechanical circulatory support (MCS) devices results in platelet dysfunction and bleeding coagulopathy. We have previously demonstrated that shear-mediated platelet dysfunction is associated with proapoptotic platelet behavior, downregulation of adhesion receptors, and decreased aggregation response to biochemical agonists. Here, we aimed to decipher molecular mechanisms contributing to shear-mediated downregulation of α IIb β 3, GPIb, GPIV, and P-selectin surface expression on platelets.

Methods: Gel-filtered human platelets were exposed to shear stress (30-70 dyne/cm², 10') in a modified plate-and-Couette viscometer. Surface expression of α IIb β 3, GPIb, GPIV, and P-selectin (CD62) on platelets and platelet-derived microparticle (PDMP) generation were detected by immunostaining and multi-colored flow cytometry. Platelets were distinguished from PDMPs by forward and side scatter vs. standard fluorescent nanobeads SPHERO™. The concentrations of soluble α IIb β 3, glycocalicin, GPIV, and P-selectin in PDMP-free platelet media post-shear were quantified by ELISA.

Results: Exposure to increasing shear stress resulted in an incremental decrease of α IIb β 3+, GPIb+, and GPIV+ platelets and an associated increase in receptor-positive PDMPs (Fig. 1A-C). Platelet GPIb and GPIV (but not α IIb β 3) surface densities decreased 36.2% and 14.2%, respectively, following 70 dyne/cm² shear. Curiously, the number of P-selectin+ platelets, PDMPs, and their P-selectin density increased slightly with the increase of shear magnitude (Fig. 1C and 1F), suggesting minor shear-mediated platelet activation. The sheared PDMPs demonstrated significantly higher receptor densities than sheared platelets (Fig. 1D-F), likely due to shear-mediated receptor redistribution from platelets to microparticles. Virtually no GPIV was detected on sheared PDMPs. Furthermore, shear rendered an increase in soluble fragments of α IIb β 3, GPIV, and P-selectin (but not GPIb) in platelet media, potentially indicating enzymatic shedding of these receptors by platelet-derived metalloproteinases.

Conclusion: Shear stress promotes downregulation of adhesion receptors α IIb β 3, GPIb, GPIV, and P-selectin on platelets via two distinct mechanisms – shedding of their soluble ectodomains and/or generation of PDMPs. Shear-mediated microvesiculation is associated with the coordinated remodeling of platelet membrane and redistribution of platelet receptors from platelets to microparticles with PDMPs expressing significantly higher levels α IIb β 3, GPIb, and P-selectin. Shear-mediated downregulation of platelet adhesion receptors jeopardizes platelet aggregability and hemostatic function contributing to device-related bleeding coagulopathy and offering novel targets for therapeutic manipulations.

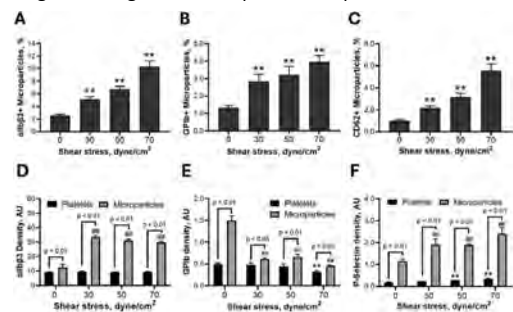


Figure 1. Shear stress promotes generation of platelet-derived microparticles enriched with platelet adhesion receptors: A, B, and C – the number of α IIb β 3+, GPIb+, and P-selectin+ microparticles; D, E, and F – surface density of α IIb β 3, GPIb, and P-selectin on platelets and microparticles. One-way ANOVA: **, - p < 0.01, as compared to the “0 Shear stress” group.

CARD3

Development And Performance Validation Of A Magnetic Levitation Ventricular Assist Device Based On A Displacement-Free Sensor

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Background: Magnetically levitated ventricular assist devices offer significant advantages over conventional mechanical bearing ventricular assist devices in terms of improved patient survival and reduced device-related complications. However, conventional magnetic levitation control systems rely on costly and bulky displacement sensors to monitor rotor displacement. Displacement-free sensing technology offers a possible solution by using position sensors instead of displacement sensors. The aim of this study was to develop and validate a magnetic levitation ventricular assist system based on displacement-free sensors.

Methods: In this study, a magnetic levitation ventricular assist system without displacement sensors was designed and fabricated, including a specially designed motor body and a low lysis impeller. The design of the system focused on improving rotor stability and reducing the risk of hemolysis. Advanced displacement-free sensing technology was used to accurately monitor rotor position, and the motor control algorithm was optimized to accommodate the displacement-free sensing configuration. System performance was evaluated by rotor stability testing (at 4 G acceleration), hemolytic performance testing in experimental animal sheep blood (vs. Centrimag system), and 150-day long-term operational testing.

Results: The experimental results showed that the displacement-sensor-free magnetically levitated ventricular assist system performed excellently in maintaining rotor stability without severe positional shifts, even under 4 G of gravitational acceleration. In addition, the hemolysis level of the system was significantly lower than that of the conventional system (0.0078 ± 0.0013 vs. 0.0120 ± 0.0022 , $p < 0.05$), demonstrating effectiveness in reducing the risk of hemolysis. The reliability and durability of the system was further confirmed by the 150-day long-term operational test.

Conclusion: The magnetic levitation ventricular assist system based on a displacement-free sensor demonstrated good stability and reliability in improving rotor control accuracy and reducing the risk of hemolysis. The application of this technology provides a new direction in the development of ventricular assist devices and is expected to lead to significant improvements in patient well-being in clinical applications.

Structure of a displacement sensor-free magnetic levitation ventricular assist device



Hemolytic Lab Test



CARD4

Derivation and validation of plasma ADAMTS13 for predicting 1-year thromboembolic events in heart failure patients undergoing LVAD implantation: a prospective validation study

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Background: Thromboembolic events (TE) after left ventricular assist device (LVAD) implantation are common and are associated with increased morbidity and mortality. Early identification and treatment of TE can significantly increase patient's survival rate. ADAMTS13 has been shown to play a vital role in thrombosis formation and can be a valuable biomarker to predict TE in several settings. The purpose of this study is to explore and validate the value of plasma ADAMTS13 in predicting TE among heart failure (HF) patients within the first year after LVAD implantation.

Methods: The study aimed to identify TE, such as ischemic stroke, pump thrombosis, and acute venous thrombosis in LVAD patients. The research was conducted on 46 HF patients who had not experienced any active thrombosis 30 days before the LVAD surgery. The study was divided into two phases: the derivation cohort (n=19) and the validation cohort (n=27). Baseline blood samples were collected 24 hours before LVAD implantation and on postoperative days 7 and 30. ADAMTS13 plasma levels were measured in all samples. The primary endpoint was to determine the occurrence of TE within one year after LVAD implantation. The cutoff value of ADAMTS13 for predicting TEEs was determined in the derivation cohort. Then, the predictive accuracy was analyzed in the validation cohort.

Results: Overall, 21 out of 46 patients developed TE within 1 year after LVAD implantation [(TE: derivation (n=7) and validation (n=13)]. At baseline, the ADAMTS13 was significantly lower in the TE group (n=20) compared to no-TE group (n=26) (**Fig.A**). Lower ADAMTS13 expression was always associated with higher TE (**Fig.B**). In the derivation cohort, ADAMTS13 showed a good performance in predicting 1-year TE, with an area under the receiver operating characteristic curve (AUC) of 0.762 (95% confidence interval (CI) 0.514-0.924, p=0.024) and an optimal cutoff value of 216.2 ng/ml (**Fig.C**). The baseline demographic in the derivation cohort indicated that age and NYHA classification are the co-factors associated with TE risk (**Table 1**). The predictive ability of TE was greatly improved by the prediction model combining ADAMTS13 with clinical risk factors of age and NYHA classification, with an AUC of 0.976 (95% CI 0.92-0.99, p=0.03) (**Fig.D**). The ADAMTS13 achieved sensitivity and specificity of 60.00% (38.55-81.47%) and 85.71% (59.79%-100%), respectively, when validated in the validation cohort.

Conclusions: Plasma ADAMTS13 level can serve as a valuable biomarker for predicting the occurrence of TE in LVAD patients within the 1st year of implantation. Close monitoring of ADAMTS13 change after LVAD implantation can help early detection of TE and initiate prompt treatment.

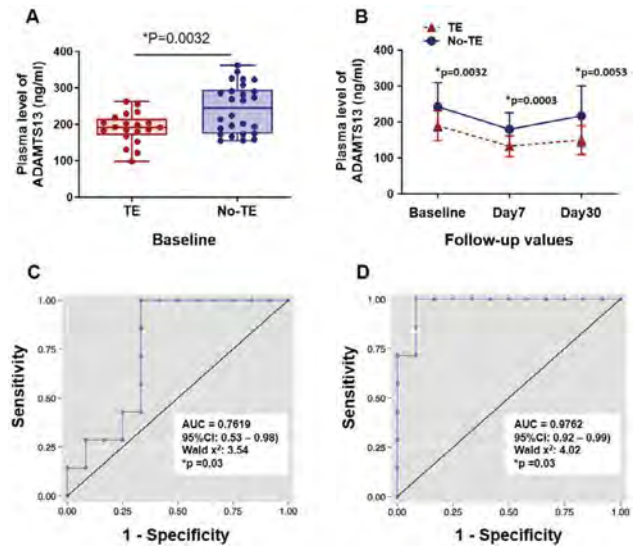


Table 1. Characteristics of LVAD patients with or without TE in derivation cohort

Derivation cohort characteristics	TE (N=7)	No-TE (N=12)	p-value
Age in years, Median (IQR)	63(59-72)	51(43-60)	0.0342*
Sex, n (% male)	5(71.43%)	8(66.67%)	1.0000
BMI, kg/m ² , Median (IQR)	25.57(21.27-30.04)	30.27(23.14-34.89)	0.1763
BSA, m ² , Median (IQR)	1.88(1.70-2.17)	2.09(1.95-2.25)	0.1083
INTERMACS profile, median (IQR)	2.67(2.00-4.00)	2.00(2.00-2.00)	0.1728
NYHA classification, median (IQR)	3.29(3.00-4.00)	3.92(4.00-4.00)	0.0211*
INR, Median (IQR)	1.52(1.15-1.40)	1.19(1.05-1.19)	0.1571
PT (seconds), Median (IQR)	17.73(14.40-16.80)	14.72(13.40-14.80)	0.1905
PTT (seconds), Median (IQR)	56.74(30.90-75.00)	49.28(30.30-67.15)	0.5982

Non-parametric One-Way ANOVA with Kruskal-Wallis Test for continuous variables (Median, IQR) and Chi-square test for categorical variables (n, %). *p<0.05 is statistically significant.

CARD5

Longitudinal Outcomes of Impella 5.5 as a Bridge to Heart Transplant- The Mayo Clinic Florida Experience

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Background: Impella 5.5 optimizes the care of heart transplant recipients by providing hemodynamic support, left ventricular unloading, physical mobility, and improvement in renal and right ventricular function despite cardiogenic shock. This study aimed to investigate longitudinal outcomes in patients bridged to transplant with Impella 5.5.

Methods: We performed a single-center retrospective study on all patients bridged to transplant since February 2020. Inclusion criteria encompassed patients with more than 730 days of post-transplantation follow-up. Data was abstracted from the electronic medical record. The primary outcome of the analysis was survival. The secondary outcome assessed major rejection episodes.

Results: During our review period, a total of 83 patients utilized Impella as BTT. Of these, 23 patients have now reached more than 2 years post-transplant. 19 underwent heart alone and four patients received heart and kidney transplants. The median age in this group was 63 (56-67), with a distribution of 9% female and 35% African American. 53% of patients presented with non-ischemic cardiomyopathy characterized by a baseline left ventricular ejection fraction of 18% (15-20.5). The median duration of Impella 5.5 support was 19 days (12.5-26), with all patients surviving to transplant. The median follow-up duration was 1024 days (946-1117) with a 91% post-transplant survival rate. Two patients died after transplant, one occurring at six months and one at 841 days. Only 4% experienced donor heart rejection requiring intervention.

Conclusion: For patients with end-stage heart failure and cardiogenic shock, these results underscore the promise of Impella 5.5 as a suitable option for bridge to transplantation and complication-free long-term follow up.

CARD6

Clinical Trial for the Evaluation of Safety of a Paracorporeal Pulsatile Ventricular Assist Device as a Bridge to Transplantation Therapy for Patients with Refractory Heart Failure

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Background: Ventricular Assist Devices (VAD) have been used since the early 1960s and have undergone multiple evolution steps aiming at better performance. The two more important steps were the change from pulsatile to continuous flow, and partial implantability; however, these changes came along with increasing costs that made the devices too expensive for emerging countries. Vitacor is a paracorporeal pulsatile VAD and a cost-effective alternative for centers that currently do not have access to VAD-based therapies other than palliative treatments. In this clinical trial, five patients with refractory heart failure were implanted with Vitacor to assess and evaluate the survival rate.

This device consists of two subsystems: 1) a disposable patient circuit, which includes the pump and the inflow and outflow cannulas that are implanted directly into the patient's heart; and 2) the control unit, which consists of two pneumatic consoles that drive the pressures applied to the pump, and the back-up station. It can be used as a right, left, or bi-ventricular mechanical circulatory support system.

Methods: The objective of this clinical trial was to evaluate the device's impact on life expectancy in patients with terminal heart failure (INTERMACS 2-3) when used as a bridge to transplantation therapy. Vitacor was implanted in five patients meeting the inclusion criteria, whose prognosis pre-implantation was fatal since they were no longer eligible for transplantation. The hypothesis of the trial was to decrease this mortality rate from a 100% to at least a 60%. Patients were constantly monitored and hemodynamic data from the VAD was recorded to verify that the device complied with its intended use and that no mechanical nor electrical malfunctions occurred. All complications were registered and classified.

Results: Three of the five patients reached the heart transplantation, thus decreasing the mortality rate from 100% to 40%, 20% more than expected for the trial's objective. The average support time was 9.8 days (SD: 3.35): 8.5 days (SD: 2.12) for patients that did not reach transplantation and 10.67 days (SD: 4.16) for the ones that did. There were 35 complications recorded, however, no adverse events nor mortality cases were device-related. Vitacor efficiently operated throughout the five patients with an average flow rate of 4.0 l/min (IQR: 0.7) as clinically required, which in turn, significantly improved their cardiac index from an average of 1.9 up to 2.29 l/min/m² (IQR: 0.37, p: 0.018) allowing better organ perfusion.

Conclusions: Vitacor maintained an adequate pump flow and performed as expected, restoring the hemodynamic demands required for each patient with no mechanical or electrical malfunctions. It safely operated with no adverse events registered, while decreasing the mortality rate more than expected. Finally, Vitacor proved to be a device that can prolong a patient's life expectancy.

CARD7

Challenging Conventions: Outcomes of Impella 5.5 Placement in Patients with Small Axillary Artery Diameters

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Background: The Impella 5.5 (Abiomed, Danvers, MA) is a micro-axial left ventricular assist device that enhances end-organ perfusion by unloading the left ventricle. Its insertion, requiring combined surgical and endovascular approaches for device delivery, can be particularly challenging in patients with small arteries. An axillary artery diameter of 7 mm or greater is recommended due to the size of the pump [21Fr]. We aimed to describe our experience of impella 5.5 placement in patients with small axillary artery and the implications on outcomes.

Methods: A retrospective analysis of all consecutive patients who underwent Impella 5.5 placement attempts at our institution from June 2020 to January 2024 was conducted. We have been exclusively using axillary approach during this period. Small axillary artery was defined as diameter < 7 mm and patients were stratified into small axillary diameter and normal diameter groups (control). Axillary diameter was measured intraoperatively and on computed tomography.

Results: A total of 67 patients in whom Impella 5.5 placement was attempted was identified of which, 11.9% (n=8) had a small diameter axillary artery, with an average diameter of 6.1±0.5mm compared to 8.8±1.2mm in the control group. Technical success rate was 95.5% (N=64/67). Patients with small diameter arteries were younger than those with normal diameters (61.1±11.7 vs 39.9±13.3 years, p<0.0001), with a numerically higher proportion of females in small diameter group (37.5% vs 16.9%, p=0.19). There were no significant differences in body mass index, peripheral vascular disease, or presence of ICD in both groups as shown in Table 1.

Despite the diameter difference, the delivery time was similar in both groups (6.7±3.6 vs. 7.0±4.1 minutes, p=0.95). Furthermore, the rate of delivery failure was not significantly different to the control group (12.5% [N=1] vs. 3.4% [N=2], p=0.31) [Table 2].

Postoperative outcomes such as development of new stroke (12.5% [N=1] vs. 12.3% [N=7], p=0.98), vascular complications (12.5%[N=1] vs. 15.2%[N=9], p=0.84), ipsilateral limb ischemia (12.5%[N=1] vs. 5.3%[N=3], p=0.47), infection (12.5%[N=1] vs 8.9%[N=5], p=0.74) and hospital mortality (37.5%[N=3] vs. 42.4% [N=25], p=0.79) revealed no significant differences between the groups.

Conclusion: Impella 5.5 placement is feasible in patients with small diameter axillary arteries, with comparable outcomes as those with normal diameters. This feasibility may be attributed to the lower prevalence of atherosclerosis in younger patients, coupled with the potential for arterial stretching during device delivery. Furthermore, intraoperative measurement can underestimate the actual diameter as arteries can be spastic in patients with cardiogenic shock. Our study suggests that diameter constraints may be more accommodating than previously considered.

	Small diameter axillary artery (<7 mm) n=8	Normal diameter (7 ≥mm) n=59	P value
ICD	3(37.5%)	20(36.1%)	0.95
PVD	0	4(7.1%)	0.29
Peri-op Variables			
Delivery Time	6.7(3.6,9)	7(4.0,11.9)	0.95
Long delivery time >20mins	1(12.5%)	5(10.2%)	0.84
Delivery failure	1(12.5%)	2(3.4%)	0.31
Vascular complication	1(12.5%)	9(15.2%)	0.83
Support level (P level)	6.1±1.7	6.6±1.4	0.39
Support duration	19(10,29.3)	12(6,17)	0.12
Stroke	1(12.5%)	7(12.3%)	0.98
Ipsilateral limb ischemia	1(12.5%)	3(5.3%)	0.47
Infection	1(12.5%)	5(8.9%)	0.74
In-Hospital mortality	3(37.5%)	25(42.4%)	0.79
Mortality on device	1(14.3%)	12(20.7%)	0.67
Reached transplantation	4(50.0%)	15(25.4%)	0.17
Recovery	2(25%)	21(35.6%)	0.71

Table 2. Details of delivery failure of Impella 5.5

	Age/ Sex	AxA diameter	Side of access	Reason for failure	Outcome
Patient 1	63/F	7.5	RAX	Calcification at right subclavian artery to innominate artery level, bleeding from anastomosis.	Impella CP through AxA.
Patient 2	69/F	6.7	RAX	Impella 5.5 was not able to pass the right subclavian artery to innominate artery junction after multiple attempts even using stiff wires.	Impella CP through AxA.
Patient 3	65/F	7.5	LAX	Diameter of the artery and atherosclerosis of the subclavian artery to the innominate artery.	Abortion

	Small diameter axillary artery (<7 mm) n=8	Normal diameter (7 ≥mm) n=59	P value
Age	39.9±13.3	61.1±11.6	<0.0001
Sex (female)	3(37.5%)	10(16.9%)	0.19
BMI	28.0±6.5	29.7±5.5	0.41
Axillary diameter	6.1±0.5	8.8±1.2	<0.0001
Right axillary artery	7(87.5%)	46(77.9%)	0.51
Indication for Impella 5.5			0.34
Recovery	2(25.0%)	23(38.9%)	
BTT	5(62.5%)	19(32.2%)	
BT-VAD	0%	8(13.6%)	
High risk surgery	1(12.5%)	7(11.8%)	
BT- decision	0	2(3.5%)	
ECPELLA	4(50.0%)	29(49.1%)	0.96
Ischemic cardiomyopathy	2(25.0%)	36(61.0%)	0.054

CARD8

Ventricular Function Improves Following Non-Blood Contacting Direct Mechanical Ventricular Actuation Compared to LVAD Support in the Small Chronically Failing Heart

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Background: Mechanical circulatory support (MCS) carries risks for infection, thromboembolic events, and bleeding. These complications are more prevalent when MCS is employed in a smaller body habitus where additional challenges of hemodilution, cannulation and device installation may arise. One promising solution is direct mechanical ventricular actuation (DMVA), which provides non-blood contacting systolic and diastolic biventricular support. DMVA has demonstrated efficacy in laboratory and clinical applications. This study compared post-support ventricular function following DMVA versus a miniaturized left ventricular assist device (LVAD) in a small animal model of chronic heart failure (CHF).

Methods: Used: CHF was induced in small mixed-breed dogs (n = 12, 16 ± 2 kg) with right ventricular overdrive pacing or serial coronary microembolization. Animals received either a continuous flow LVAD (n = 5) or DMVA (n = 7) for two hours. LV pressure/volume evaluations with and without dobutamine infusion (1, 5, 10 and 20 ug/kg/min) were performed before and after support. LV pressure/volume relationships and dobutamine responses were compared between LVAD and DMVA. Pre- and post-support data were analyzed using paired Student's t-tests within support groups. Mean differences in dobutamine responses were assessed between groups using a three-way (treatment, time-point, dobutamine dose) ANOVA test with repeated measures, followed by Tukey's multiple comparison post-hoc tests.

Results: All animals demonstrated depressed cardiac function consistent with CHF. There were no significant changes in heart rate, mean pressures, LV volume, or cardiac output between pre- and post-support periods for either device. DMVA improved post-support preload recruitable stroke work and end-diastolic pressure-volume relationships with tendencies toward more negative -dP/dt_{min} while these post-support measures of LV function tended to be decreased following LVAD (Table 1). Cardiac reserve measured by systolic (+dP/dt_{max}) and diastolic (-dP/dt_{min}) responses to dobutamine were significantly reduced following LVAD vs DMVA support (Table 2).

Summary: Post-support systolic and diastolic LV performance was improved following two hours of DMVA. LVAD support had no positive impact on subsequent LV performance. Cardiac reserve was also better following DMVA vs LVAD support. Previous work has demonstrated DMVA resulted in improved cardiac function compared to continuous flow MCS in the acutely failing heart. Miniaturized DMVA devices have been used to support the acutely failing rabbit heart. This study demonstrated cardiac function improves following DMVA support in a small canine model of CHF. No such benefit was observed following LVAD support. Improved diastolic function following DMVA is noteworthy and may be a therapeutic effect of diastolic assist. These results further indicate DMVA's potential in treating adult and pediatric patients with heart failure.

Table 2.

Post-Support		Dobutamine Challenge (ug/kg/min)					P-value
		0	1	5	10	20	
HR (bpm)	DMVA	112 ± 6	112 ± 9	117 ± 6	128 ± 18	145 ± 17	0.662
	LVAD	97 ± 9	97 ± 9	106 ± 8	116 ± 7	130 ± 13	
MBP (mm Hg)	DMVA	78 ± 7	90 ± 10	108 ± 13	109 ± 12	102 ± 9	0.004
	LVAD	54 ± 8	62 ± 8	77 ± 10	72 ± 6*	60 ± 3*	
+dP/dt _{max} (mm Hg/s)	DMVA	1109 ± 136	1466 ± 255	2799 ± 646	3555 ± 729	4452 ± 928	0.019
	LVAD	823 ± 82	1090 ± 77	1894 ± 271	2317 ± 379	2581 ± 392*	
-dP/dt _{min} (mm Hg/s)	DMVA	-1406 ± 237	-1837 ± 336	-2821 ± 550	-3033 ± 544	-3158 ± 535	0.034
	LVAD	-859 ± 57	-1140 ± 78	-1771 ± 261	-2022 ± 420	-1872 ± 394*	

Comparison between DMVA and LVAD Post-Support Dobutamine Responses. *p<0.05 vs. DMVA

Table 1.

		Inotropy		Lusitropy	
		dP/dt _{max} (mm Hg/s)	PRSW (mm Hg)	dP/dt _{min} (mm Hg/s)	EDPVR (mm Hg/mL)
DMVA	Pre	1042 ± 171	34 ± 6	-1194 ± 263	0.7 ± 0.1
	Post	1109 ± 136	46 ± 6	-1406 ± 237	0.5 ± 0.1
	%	16 ± 13	29 ± 7	33 ± 17	-28 ± 9
	P-value	0.362	0.003	0.069	0.036
LVAD	Pre	951 ± 60	38 ± 11	-1147 ± 194	0.8 ± 0.2
	Post	823 ± 82	47 ± 5	-859 ± 57	0.9 ± 0.1
	%	-11 ± 13	24 ± 23	-17 ± 14	13 ± 18
	P-value	0.372	0.227	0.270	0.707

Measures of Systolic and Diastolic Function Pre- and Post-Support for DMVA and LVAD

CARD9

Hemocompatibility of Bivalirudin and Bicarbonate as Adjunctive Therapy for Heparin Replacement in Catheter-based Axial Flow System
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Background: The Impella® catheter blood pump (Abiomed) is effective for rapid hemodynamic restoration in patients with AMI cardiogenic shock and acute decompensated heart failure. These patients are typically placed on systemic heparin due to enhanced underlying thrombotic risk. The Impella® system relies on local internal perfusion of a heparin-containing purge solution during operation. The combination of systemic and local heparin infusion often contributes to variable degrees of overall anticoagulation with increased bleeding risk. To reduce variability in anticoagulation efforts have been ongoing to eliminate heparin. In prior work we advanced sodium bicarbonate as an alternative to local purge heparin, demonstrating efficacy, leading to FDA clearance for this use. Here, we investigate the use of bivalirudin, a direct thrombin inhibitor, as an alternative to systemic heparin in a mock loop environment with circulating whole blood. We hypothesize that systemic bivalirudin combined with local sodium bicarbonate purge solution will have similar or improved blood hemocompatibility as compared to systemic heparin with the same purge.

Methods: Adult, male pigs (N = 10; 58-70kg) were bolus injected with heparin (100 IU/kg) or bivalirudin (0.75mg/kg) IV. Blood was collected via femoral catheter directly into 10% v/v citrate (CPD), and immediately loaded into mock circulatory loop consisting of connected Tygon tubing. Impella5.5® was run for 4 hours with purge solution (25mEq/L sodium bicarbonate in D5W) for experiment duration. Loop pressure (60 mmHg), temperature (37 C), and pump flow rate (4.2-5L/min) were all maintained during operation. Samples were collected serially (q30 min.) and analyzed for hemolysis and flow cytometry analysis of platelets (CD31 and CD62P). Non-circulating ("Rest") blood samples at identical time points served as control.

Results: Free hemoglobin, as indicator of hemolysis, increased over time under all experimental conditions (Fig.1A). Average hemolysis was significantly higher with systemic heparin vs. bivalirudin following 150 minutes (16mg/dL difference) of circulation. This trend continued through 240 minutes (28mg/dL difference). No significant difference in P-selectin exposure on platelet surfaces was found between experimental conditions (Fig. 1B). However, an average decrease in P-selectin positive platelets was observed over time. This decrease was on average less pronounced in systemic bivalirudin conditions.

Conclusion: Systemic bivalirudin and sodium bicarbonate purge solution led to similar or improved hemocompatibility (hemolysis, P-selectin) as compared to systemic heparin and sodium bicarbonate purge solution. Use of bivalirudin as a systemic anticoagulant in conjunction with sodium bicarbonate purge solution is promising for Impella® use. This approach offers the potential to create an overall heparin-free system simplifying anticoagulation management, with overall reduced bleeding risk.

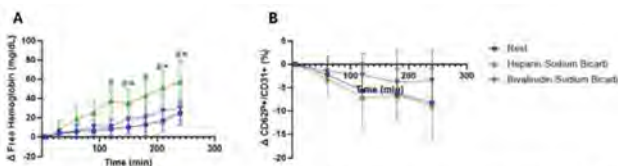


Figure 1. Porcine whole blood was collected from non-circulating ("Rest") samples and from samples circulated with Impella5.5 using sodium bicarbonate (25mEq/L in D5W) purge solution. Pigs were anticoagulated with either heparin (100IU/kg; "Heparin-Sodium Bicarb") or bivalirudin (0.75mg/kg; "Bivalirudin-Sodium Bicarb") prior to blood collection and circulation. Blood samples were analyzed for (A) plasma free hemoglobin and processed for flow cytometric analysis. Platelets were positively identified with anti-CD31 and then analyzed for (B) %positive platelet population of P-selectin using anti-CD62P. All data are offset from t = 5-minute measurements to better compare between experimental conditions at each time point. Values are reported as mean ± standard deviation. Data were collected and pooled from N = 10 pigs; # indicates p < 0.05 between "Rest" and "Heparin-Sodium-Bicarb"; x indicates p < 0.05 between "Heparin-Sodium-Bicarb" and "Bivalirudin-Sodium-Bicarb".

CARD10

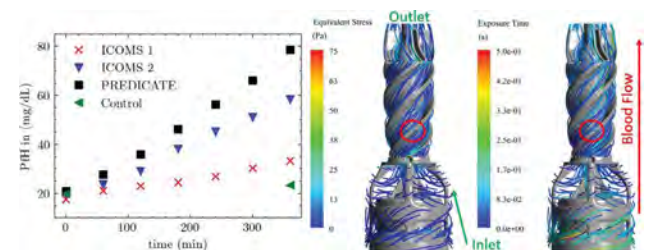
In-Vitro And In-Silico Evaluation Of The Hemolytic Levels Of A Novel Wireless Intraventricular Assist Device.

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Background: Due to the scarcity of heart donors, ventricular assist devices (VADs) are the only treatment option for most patients with end-stage heart failure. However, current devices are known to induce threatening adverse events such as bleeding, stroke, or infection. In this context, the FlowMaker®, a novel intraventricular assist device, provides a synchronized pulsatile operating mode that adds pump-induced flowrate (1.5-3.5 L/min) to the native one, favoring efficient recovery. The pump is wireless and fully implantable, resolving infection complications. The inlet and outlet of the pump are located inside the left ventricle, avoiding the need for bypass and taking advantage of the native heart ejection. In-vitro and in-silico hemolysis experiments were carried out to assess the hemocompatibility of this new device.

Methods: In-vitro hemolysis tests were performed using porcine blood following the ASTM F1841 standard at ac.biomed (Aachen, Germany). Three pumps were tested at the same time (two FlowMakers and one predicate-approved device). The FlowMaker was programmed in the worst hemolytic condition, which corresponds to its highest rotational speed (2000-6000 rpm). In contrast, the reference device was programmed at 5 L/min, which according to the manufacturer is an operating point of low hemolysis (< 0.1 g hemoglobin per 100 L of blood). Numerical simulations were conducted to predict the hemolytic level and identify the critical points of the device. Computational fluid dynamics (CFD) simulations were conducted using ANSYS CFX. A transient sliding mesh approach was used along with the k-omega SST turbulence model and proper boundary conditions. A credibility assessment of the simulations was performed following FDA guidelines. The assessment contained velocity field validation thanks to PIV experiments and a grid convergence study. The modified index of hemolysis was computed in the simulation using a power-law model based on a standard transport equation.

Results: Plasma free hemoglobin (PfH) was lower for both FlowMakers tested compared to the predicate device (see Figure A). The modified index of hemolysis predicted by the CFD simulation, $MIH_{CFD} = 1.2$, was inside the uncertainty range of the experimental value ($MIH_{in-vitro} = 2.14 \pm 1.02$). Figure B) and C) show the equivalent shear stress and exposure time, respectively, over representative streamlines. Overall, the equivalent shear stress values remain low along streamlines (< 10 Pa). The regions related to high shear stress values present low exposure times (~0.1s) limiting the cell damage potential. This effect can be observed over the impeller tip clearance marked in the red circles. In conclusion, FlowMaker-induced hemolysis has been demonstrated to be under that of a predicate-approved device, while our in-silico methodology is suitable for further hemolysis impact assessment.



CARD11

Early-Stage Development of the CoRISMA Mechanical Circulatory Support (CMCS) System for Heart Failure Therapy

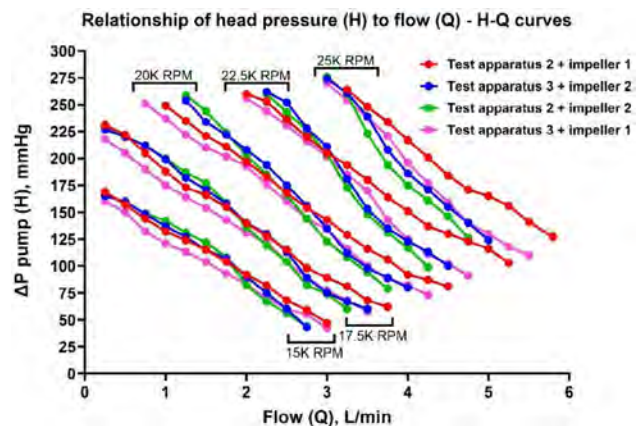
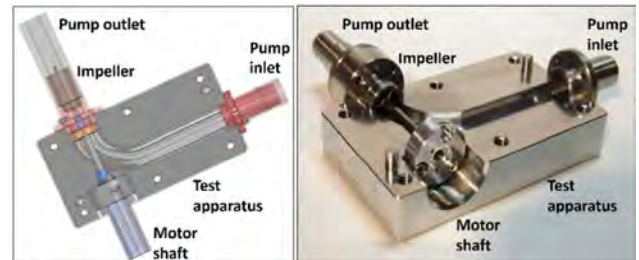
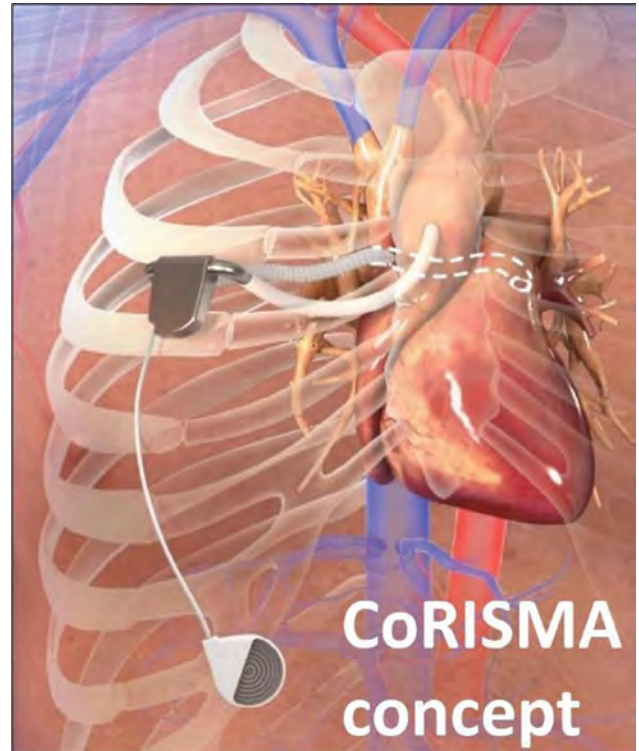
Gretel Monreal¹, Steven C. Koenig², James F. Kelley³, Jessica J. Illg³, Daniel Tamez³, Mark S. Kelley³, Daisy P. Cross³, Michael E. Theran³, Mark S. Slaughter¹; ¹Cardiovascular and Thoracic Surgery, University of Louisville, Louisville, Kentucky, United States, ²CT Surgery and Bioengineering, University of Louisville, Louisville, Kentucky, United States, ³CoRISMA MCS Systems, Inc., Hamden, Connecticut, United States

Background: CoRISMA MCS Systems Inc (Hamden CT) is developing an innovative mechanical circulatory support system (CMCS) as a durable therapeutic option for end-stage heart failure (HF) patients. The system is comprised of an axial flow pump, non-contacting hydrodynamic bearings, and integrated DC motor designed to be fully implantable in a left atrial (LA) to aortic (Ao) configuration; this unloading strategy may be particularly beneficial for HF patients with preserved ejection fraction (HFpEF). The small, compact device design should allow for a less invasive off-pump implant. We present early-stage engineering development and testing of the prototype CoRISMA pumps.

Methods: Computational fluid dynamics (CFD) modeling was performed to evaluate flow and shear in two impeller designs (3 blades, 0.5 mm thickness, 8.9 mm diameter, 0.15 mm gap, polished titanium) and stator (5 blades, polished titanium). Test apparatuses were custom built to expedite development of the impeller designs and iteratively refine the CFD models. Two candidate impeller designs were fabricated. The impellers and pump components were assembled and tested in each of the two test apparatuses (n=4 impeller + test fixture configurations) in static mock flow loops (hydrodynamic H-Q curves, 3.5cP glycerol solution at 37°C), and in dynamic mock flow loops (hemodynamics, 3.5cP glycerol solution at 37°C) tuned to HF conditions (mean aortic pressure 50 mmHg, central venous pressure 15 mmHg, aortic flow 3.0 L/min, and heart rate 80 bpm).

Results: CFD predicted flow dynamics for impellers 1 and 2 were 4.56 L/min and 4.82 L/min, respectively, at 100 mmHg. Impeller 2 required less torque to generate a 6% increase in fluidic flow, and the stator had a larger area of high pressure, indicative of lower friction, which likely contributed to the increased efficiency. Experimental testing for all four configurations in the static and dynamic mock loops met performance metrics as evidenced by generating 4.0-4.5 L/min flow against 70-76 mmHg pressure at 25,000 rpm and restoring hemodynamics in the dynamic mock flow loop from baseline simulated HF test conditions.

Conclusion: These results demonstrate proof-of-concept of the early engineering design and performance of the prototype CoRISMA pumps. Engineering specifications, challenges observed, and proposed solutions for the next design iteration were identified for the continued development of an effective, reliable, and safe LA-to-Ao CMCS system for HF patients. Current design plans are underway for incorporating a wireless energy transfer system for communication and power, eliminating the need for and complications associated with an external driveline, to achieve a fully-implantable system.



CARD12

Revolutionizing Pediatric Heart Transplantation through Hypothermic Oxygenated Perfusion (HOPE).

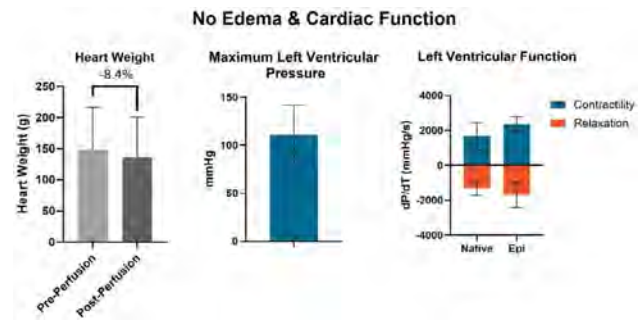
Kristina Andrijauskaite, Rafael Veraza, Riley Lopez, Zachary Maxwell, Isabella Cano, Exal Cisneros, Maria Basurto, Chelbee Farnen, George Lamberson, Tyler Dean, Leonid Bunegin; *Vascular Perfusion Solutions, Inc, San Antonio, Texas, United States*

Background: Pediatric device innovation has not kept pace with advancements in the adult domain, with only 24% of class III medical devices approved for pediatric use over the last decade, typically for children aged 12 and above. Currently, pediatric patients requiring heart transplants lack access to innovative organ preservation devices due to the absence of suitable options for preserving pediatric-sized hearts with appropriate physiological flows and perfusion pressures. This pilot study aimed to assess the safety of the novel, portable, and user-friendly hypothermic cardiac preservation device, using pediatric-sized cardiac grafts.

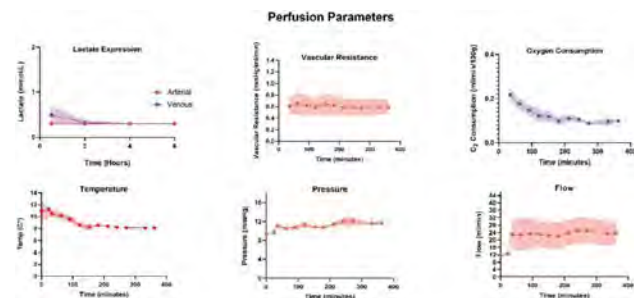
Methods: Porcine hearts (n = 5) were preserved ex-vivo using an adapted version of the VP.S ENCORE® cardiac preservation device at hypothermic temperature for up to 6 hours. The primary study endpoints were to ensure that the device could deliver low perfusion pressures and flows to adequately maintain cardiac viability and function. Hourly flow, pressure, temperature, and blood gas measurements were taken from perfused hearts followed by the cardiac function assessment on the Langendorff.

Results: The average recorded temperature during preservation was $8.9 \pm 1.21^\circ\text{C}$ with a mean pressure of 11.20 ± 1.07 mmHg and a flow of 22.95 ± 12.50 ml/min. The heart weight before preservation ranged from 57 to 218 g (148.5 ± 67.60 g) leading to weight loss post-perfusion (-8.4%). Mean oxygen consumption was 0.13 ± 0.05 ml O₂/min/100g. Levels of lactate for both arterial and venous samples were below 0.7 mmol/L across all experiments. Native left ventricular contractility and relaxation measured by dP/dT was 1671 ± 785.9 and -1308 ± 425.1 mmHg/s respectively, indicating normal cardiac function. Left ventricular contractility and relaxation with administration of inotropic support (Epi 0.25 mg injected arterial) was 2367 ± 441.5 and -1685 ± 736.6 mmHg/s respectively, with a 41.6% increase in contractility and 28.8% increase in relaxation. Further, gene expression of endothelial markers and histopathology assessment demonstrated an intact endothelium post-preservation.

Conclusions: To the best of our knowledge, this pilot study is the first of its kind to demonstrate successful prolonged preservation of pediatric cardiac grafts in a hypothermic oxygenated machine perfusion system beyond the standard of care. The VP.S ENCORE® device's versatile perfusion pressure range allows for the safe preservation of pediatric-size cardiac grafts, without damaging their anatomical structure and maintaining cardiac function post-preservation. Future studies include its use in an orthotopic animal model to evaluate safety before moving on to a pediatric clinical trial. The findings of this study give HOPE for enhancing heart transplant rates among underserved populations of pediatric patients.



No Edema & Cardiac Function.



Perfusion Parameters.

CARD13

Interaction of a Ventricular Assist Device with Patient-Specific Cardiovascular Systems - In-Silico Study with Bidirectional Coupling

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Background: Ventricular assist devices (VADs) are used to assist the heart function of patients with advanced heart failure. Computational fluid dynamics is widely employed in the development and optimization of VADs, particularly for assessing factors such as blood damage. Ensuring the accuracy of these simulations requires precise incorporation of the VAD's operating conditions.

Patients relying on VAD support often exhibit residual cardiac pulsatility, causing the VAD to operate in conjunction with the still-beating heart. This interaction introduces pulsating flow conditions, leading to dynamic changes in operational points from partial load to overload and vice versa. Consequently, VADs may undergo significant variations in pressures and flow rates during operation. In certain patients, specific characteristics of the cardiovascular system can result in non-ideal operation points, potentially increasing blood damage. It is crucial to account for all these factors in flow simulations to accurately represent the complex dynamics involved in VAD operation.

Therefore, this study aims to address this issue by evaluating the flow in a VAD interacting with patient-specific cardiovascular systems in three different heart failure patients.

Methods: This study introduces a novel numerical method incorporating a patient-specific cardiovascular system model bidirectionally coupled with a 3D flow simulation of the HeartMate 3. The cardiovascular system is represented by a lumped parameter model, utilizing clinical data from end-stage heart failure patients. Specifically, three heart failure patients with different cardiac activities are considered.

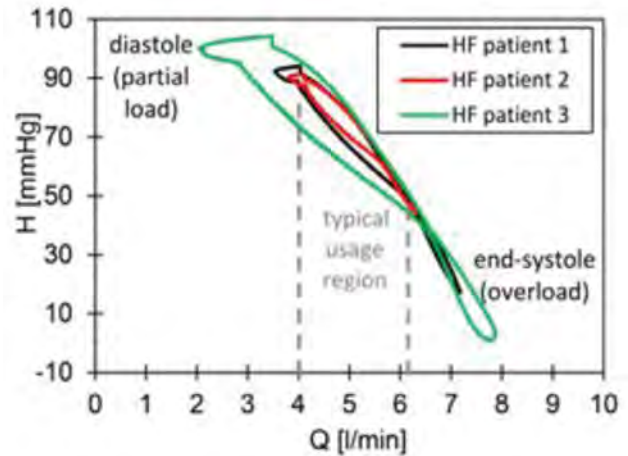
Various parameters of both the cardiovascular system and the VAD are examined. This includes an assessment of flow rates, pressures, VAD heads, efficiencies, and as crucial parameter—the blood damage potential of the VAD. The latter is accounted for using a transport equation for plasma-free hemoglobin.

Results: The head-flow rate curve of the VAD exhibit a pronounced hysteresis, with the degree of hysteresis increasing in correlation with the remaining heart activity. Additionally, a more vigorous heartbeat compels the VAD into less favorable operating conditions, particularly in overload and strong partial load conditions, where stresses and stress exposures reach their maximum, respectively. Both overload and, notably, partial load conditions during pulsating operation result in elevated blood damage potentials.

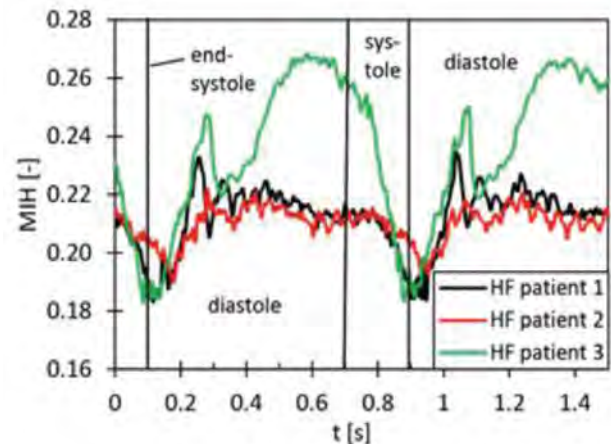
Conclusion: This study yields significant insights into the dynamic behavior of VADs in conjunction with patient-specific cardiovascular systems, highlighting the challenges posed by residual cardiac pulsatility. The findings emphasize the critical role of incorporating patient-specific characteristics in computational simulations for accurate assessments.

The novel bidirectional coupling method holds promise in simulating

realistic flow environments, closely resembling the actual operational conditions of VADs.



Comparison of the dynamic H - Q curves with hysteresis at $n = 5500$ rpm in interaction with the three heart failure (HF) patients. The gray areas mark the “typical usage region” of the VAD according to *Heatley G et al.; MOMENTUM 3 Investigators. Clinical trial design and rationale of the Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy With HeartMate 3 (MOMENTUM 3) investigational device exemption clinical study protocol. The Journal of Heart and Lung Transplantation 2016;35(4):528–36.*



Modified index of hemolysis (MIH) over two heartbeats for the three heart failure (HF) patients.

CARD16

Polymeric transcatheter aortic valve (TAV) as a viable substitute for tissue-based valves: progression of a novel PolyV-2 device

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Background: As a minimally invasive 8 to surgical valve replacement, Transcatheter aortic valve replacement (TAVR), has rapidly expanded to include lower-risk patients. However, as TAVR is increasingly considered for younger patients, concerns related to the limited durability and thromboembolic risk of tissue-based valves have become more pronounced. To address these challenges, we computationally optimized, and extensively tested a polymeric TAV named PolyV-2 (27 mm, PolyNova Cardiovascular Inc, Stony Brook, NY).

Methods: The design process of PolyV-2 involved in-depth *in silico* simulations, incorporating finite element analysis (FEA) to optimize the radial force of the stent frame and minimize leaflet stresses throughout the cardiac cycle (Figure A, B) with a novel variable thickness leaflet. PolyV-2 features a sutureless design achieved by coating the nitinol stent with our "Flexamer" polymer, eliminating the challenges and costs associated with hand suturing in the manufacture of tissue valves. The valve polymer was subjected to rigorous *in vitro* testing: accelerated wear durability testing (Figure E), platelet activation rate (PAR) evaluation, assessment of calcification risk through wear testing in a pro-calcific medium, and deployment studies in *ex vivo* ovine hearts with pulsatile flow (Figure D). The hydrodynamic performance of the valve was evaluated with standard ISO-5840 (2021) testing (Figure C).

Results: Implementing a variable thickness leaflet design resulted in the PolyV-2 demonstrating a substantial reduction in peak and mean stresses throughout the cardiac cycle. The leaflets successfully (without reduction in performance or failure) underwent accelerated wear testing for 1 billion cycles, equivalent to 25 years *in vivo*, surpassing the FDA's minimum requirement of 200 million cycles. Material testing showed favorable hemocompatibility conditions, with PAR lower than a commercial tissue TAVR device and comparable to a surgical device. Pro-calcific wear testing revealed no deposition of calcific salts within the polymer leaflet, as confirmed by μ CT imaging. PolyV-2 exceeded commercial tissue valve hydrodynamic performance ($>2.0 \text{ cm}^2$) and deployment testing demonstrated adequate radial force for anchoring required for ongoing ovine animal trials.

Conclusion: To address persistent complications associated with tissue-based TAV devices, the polymeric PolyV-2 valve underwent thorough *in silico* optimization and *in vitro* testing. The results indicate superior hemodynamics, performance, and durability compared to current tissue valves. Considerations of design and material are crucial for successful translation, demonstrating enhanced bio/hemocompatibility, and progressing PolyV-2 through ongoing animal trials.

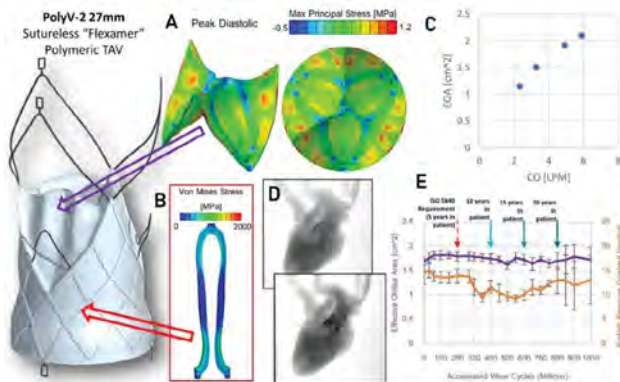


Figure 1 – (Left) Rendering of the novel polymeric PolyV-2 TAV. (A) Max Principal stress of the polymeric leaflets during diastolic closure. (B) Von Mises stress of the fully 16F crimped strut. (C) Effective orifice area [EOA] vs the cardiac output [CO] hydrodynamic performance of PolyV-2. (D) Angiograms of *ex vivo* ovine heart flow loop with pulsatile flow. (E) Accelerated durability testing of the leaflets.

CARD17

Determination of Ideal Coronary Flow Rates for Prolonged Normothermic Ex-Vivo Heart Perfusion

Wyeth D. Alexander, Kristopher A. Urrea, Vikramjit Chakraborty, Takahiro Nakashima, Robert H. Bartlett, Alvaro Rojas-Pena, Daniel H. Drake; Surgery, University of Michigan, Ann Arbor, Michigan, United States

Background: Normothermic ex-vivo heart perfusion (NEHP) is a rapidly advancing technology; however, current NEHP systems remain limited to 6–8 hours with an incomplete understanding of ideal NEHP management parameters. The goal of this current study is to better define the optimal coronary perfusion flow rate for prolonging ex-vivo heart perfusion.

Methods: Nine adult-size pigs (54.3 $\pm$ 7.1 kg) were instrumented under general anesthesia prior to heart procurement. Back table heart preparation included placement of cannulas for: 1) aorta and left atrium (LA) perfusion; 2) pulmonary artery (PA) drainage; 3) left atrial (LA) perfusion; 4) LA pressure monitoring; 5) left ventricular (LV) drainage. On circuit, hearts were maintained via Langendorff perfusion and managed with 22 kDa hemofiltration and electrolyte replacement. There were 3 experimental groups, with varying rates of perfusion: 1.5 cc/g of cardiac tissue/min ("Highflow" (HF), n=3), 0.75 cc/g/min ("Mediumflow" (MF), n=3), and 0.25 cc/g/min ("Lowflow" (LF), n=3). Data collection entailed: Q30min hemodynamic monitoring, Q1h ABGs/VBGs, Q6h LA perfusion testing (at fixed flow rate of 0.75 cc/g of cardiac tissue/min), Q24h echocardiogram, final pathology, and dry/wet weight ratios.

Results: All 9 experimental hearts completed 24 hours of NEHP. Final LA perfusion testing demonstrated aortic and mitral valvular incompetency in 2 of 3 LF hearts with gross evidence of endocardial ischemia on autopsy, 0 of 3 MF hearts, and 0 of 3 HF hearts.

24hr to baseline interventricular septal diameter (IVSD) ratio demonstrated greater net increase of IVSD in HF hearts compared to MF hearts (HF 2.56 $\pm$ 0.41 vs MF 1.80 $\pm$ 0.17; p = 0.041) but no difference between MF and LF hearts (MF 1.80 $\pm$ 0.17 vs LF 1.93 $\pm$ 0.38; p = 0.640). A similar trend was seen with 24hr to baseline left ventricular end-diastolic volume ratios (HF 0.30 $\pm$ 0.18 vs MF 0.68 $\pm$ 0.16; p = 0.050, MF 0.68 $\pm$ 0.16 vs LF 0.47 $\pm$ 0.17; p = 0.180). No difference in 24hr to baseline left ventricular ejection fraction (LVEF) ratio was observed (HF 0.48 $\pm$ 0.31, MF 0.34 $\pm$ 0.06, LF 0.20 $\pm$ 0.23) however 2/3 LF hearts demonstrated valvular incompetency which artificially augmented LVEF. When removing outliers, there existed a reduced LVEF ratio in LF hearts (MF 0.34 $\pm$ 0.06 vs LF 0.061 $\pm$ 0.001; p = 0.0088).

Final pathology and dry/wet ratio results are pending.

Conclusions: Current commercial NEHP systems remain limited to 6–8-hour storage times with recommended coronary flow rates exceeding 2 cc/g of cardiac tissue/min. The current study demonstrates a HF perfusion method maintains tissue viability at the expense of increased interstitial edema while a LF perfusion method limits interstitial edema at the expense of maintaining tissue viability. An optimal intermediate coronary flow rate offers adequate tissue perfusion while minimizing interstitial edema. These findings can be applied to current clinical practice to successfully prolong ex-vivo heart perfusion.

CARD18

48 Hour Normothermic Ex-vivo Heart Perfusion with Modified Plasma Supplementation: An Early Series

Wyeth D. Alexander, Kristopher A. Urrea, Vikramjit Chakraborty, Takahiro Nakashima, Robert H. Bartlett, Daniel H. Drake, Alvaro Rojas-Pena; *Surgery, University of Michigan, Ann Arbor, Michigan, United States*

Background: Current use of static cold storage or commercially available normothermic perfusion devices mandates organ implantation within 6-8 hours of procurement. Our previously presented data demonstrated the ability to prolong normothermic ex-vivo heart perfusion (NEHP) time in sheep to 72 hours by cross-circulating plasma from live paracorporeal sheep to the isolated hearts. This discovery begged to elucidate the agent(s) filtered and/or supplied via this cross circulation which enable prolonged NEHP success. We now present an early series of 4 porcine hearts successfully maintained for 48 hours on NEHP with modified plasma supplementation.

Methods: Four adult sized pigs (57.4 ± 4.1 kg) were placed under general anesthesia prior to heart explantation. Back table heart preparation included placement of cannulas for: 1) aorta and left atrium (LA) for perfusion; 2) pulmonary artery (PA) drainage; 3) LA pressure monitoring; 4) left ventricular (LV) drainage. Donor porcine serum was prepared via filtration through a 100 kDa or 65 kDa hemoconcentrator (SF100 and SF65, respectively). On circuit, hearts were maintained via Langendorff perfusion with a fixed flow rate of 0.75 cc/g of cardiac tissue/min and managed with 22 kDa hemofiltration, electrolyte replacement, fixed rate vasoactive medications, and SF100 or SF65 supplementation. Data collection included: Q30min hemodynamic monitoring, Q1h ABGs/VBGs, Q6h LA perfusion testing, Q24h echocardiogram, final pathology, and dry/wet weight ratios. Early termination parameters were lactate increase by 1.0 mmol/L x 2 consecutive hours, or loss of mitral valve competency without improvement following epi challenge.

Results: All hearts successfully completed 48 hours of NEHP. Key perfusion parameters during NEHP of each heart are summarized in Figure 1 (attached).

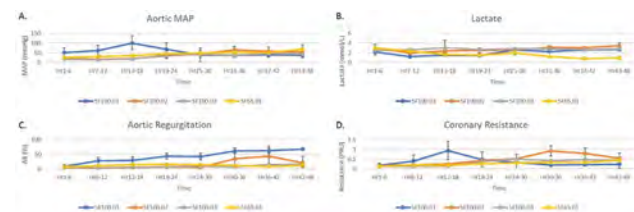


Figure 1. Hemodynamic and metabolic trends during NEHP A.) Aortic mean arterial pressure B.) Lactate C.) Aortic regurgitation D.) Coronary resistance

Q24h echocardiogram demonstrated an average increase in interventricular septal wall diameter of 15.3% ± 24.4% at 24hr and 8.3 ± 31.4% at 48hr time points. Left ventricular ejection fraction was measured and averaged; 69.7 ± 2.8% *in vivo*, 52.9 ± 20.7% at Hr0 of time on circuit, 44.0 ± 4.5% at Hr24, and 26.1% ± 10.7% at Hr48 which increased to 49.8% ± 14.3% with epi challenge. Notably, measurements of NEHP stroke volume were obtained at 0.75cc/g of cardiac tissue/min flow, providing reduced pre-load volume compared to *in vivo* measurements. Final pathology and dry/weight ratios are pending.

Conclusion: The development of prolonged NEHP devices allows for a myriad of improvements in the field of transplantation including expansion of the donor pool, assessment and treatment of marginal organs, and individual gene therapy and immunomodulation of organs prior to implantation. These data suggest that NEHP with the addition of hemofiltration and modified serum successfully preserves viable hearts for 48hr.

CARD19

In vitro assessment of hemolysis and von Willebrand Factor degradation in the fifth generation magnetically levitated PediaFlow Ventricular Assist Device

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Background: The PediaFlow is a miniature fully-magnetically-levitated axial-flow heart-assist device designed to provide chronic circulatory support for pediatric patients with congenital or acquired heart failure. This study was conducted to assess freedom from hemolysis and von Willebrand Factor (vWF) degradation of the current generation device, PF5, in-vitro with ovine blood.

Methods: Two recirculating blood flow loops were assembled to perform paired evaluation of the PF5 against the Centrimag (Abbott Laboratories, Abbott Park, IL) which served as control. The circuits were comprised of a modified PVC blood bag, Tygon® tubing, polycarbonate connectors, Hoffman clamp, Transonic flow meter, and a digital manometer, as depicted in Figure 1. The priming volume was 150 ml. Both pumps were tested at 2.5 L/min and 100 mmHg. Citrated whole blood from sheep was sourced from the Lampire Biological Labs (Pipersville, PA) and was used the following day. Prior to testing, the loops were passivated by circulating a 1% BSA solution for at least 30 minutes. The test spanned two hours and blood samples were collected at 30-minute intervals. Plasma free hemoglobin levels were measured using the Cripps spectrophotometric method. vWF antigen (vWF:Ag) ELISA assays measured plasma protein levels, while vWF collagen binding (vWF:CB) assays assessed multimer binding capacity. Electrophoresis and immunoblotting were performed to quantify the loss of high molecular weight vWF multimers.

Results: Hemolysis results for PF5.10 and the vWF:CB/Ag ratio for PF5.10 and Control pumps (n=5) are presented in Figure 2. The average NIH for PF5.10 was 0.0037, indicating a consistent improvement compared to previous generations of PF5 prototypes. This improvement is largely attributed to advancements in surface finish and component fitting within the pump flow path.

Conclusion: These results suggest that the inherent maglev design of the PF5 pump with large blood flow gaps is hemocompatible, with potential for further refinement through advanced polishing and manufacturing techniques. The vWF:CB/Ag ratio in PF5 shows a minor reduction compared to the control pump at the 2-hour mark. Ongoing tests aim to extend the runtime of the tests to enhance the signal.

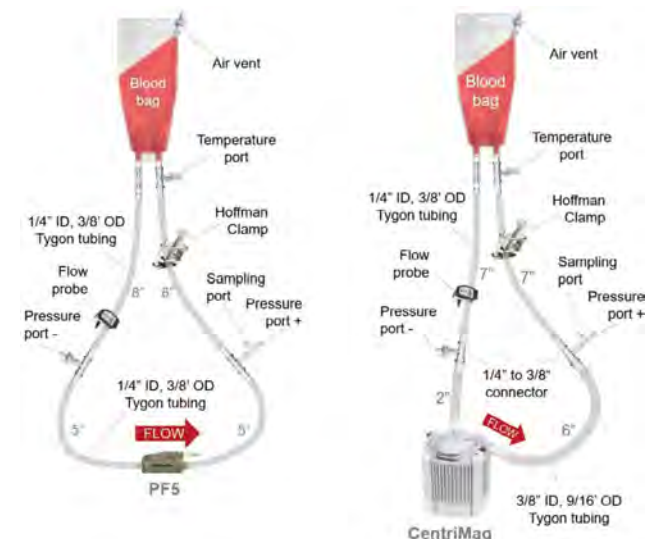


Figure 1. In vitro testing flow loops for PF5 (left) and Control (right) pumps.

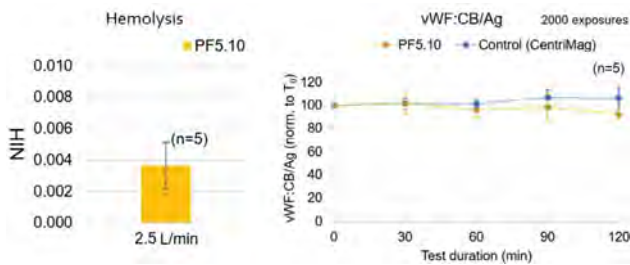


Figure 2. Hemolysis and vWF degradation results at 2.5L/min, 100 mmHg (n=5).

CARD20

A Cardiac Support Device (ASD Device) Repeatedly Delivers Bone Marrow Stem Cells To The Epicardium In Advanced Heart Failure

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Background: Ventricular restraint therapy is a non-transplant surgical option for the management of advanced heart failure (HF). To improve therapeutic applications, it is hypothesized that the active hydraulic ventricular attaching support system (ASD) has remarkable capabilities not only in delivering stem cells but also in dilated ventricles.

Methods: Male Sprague-Dewly (SD) rats were divided into four groups: normal, HF, HF+ASD, and HF+ASD-BMSCs, respectively. HF was developed by left anterior descending (LAD) coronary artery ligation in all groups except the normal group.

Results: Post-infarction electrocardiography (ECG) and brain natriuretic peptide (BNP) revealed abnormal heart function in all model groups, with the HF+ASD-BMSCs group showing significant improvement on day 30 when compared to the other HF and HF+ASD groups. Masson's trichrome staining was used to study the histology, and a large blue fibrotic area has been observed in the HF and HF+ASD groups, and quantification of fibrosis was assessed. ASD-treated rats showed normal heart rhythm, as demonstrated by a smooth ST segment and asymmetrical T-wave. The mechanical functions of the heart, such as left ventricular systolic pressure (LVSP), left ventricular end-diastolic pressure (LVEDP), and heart rate, were brought back to normal when treated with ASD-BMSCs. This effect was more prominent than that of ASD therapy alone. In comparison to the HF group, the SD rats in the HF+ASD-BMSCs group showed a significant decline in BNP levels.

Conclusion: So ASD can deliver BMSCs to the cardiomyocytes successfully and broaden the therapeutic efficacy in comparison to the restraint device alone. An effective methodology to manage end-stage HF has been proven.

Keywords: heart failure; myocardial remodeling; bone marrow stem cells; ASD device; cardiac support device; ventricular restraint therapy.

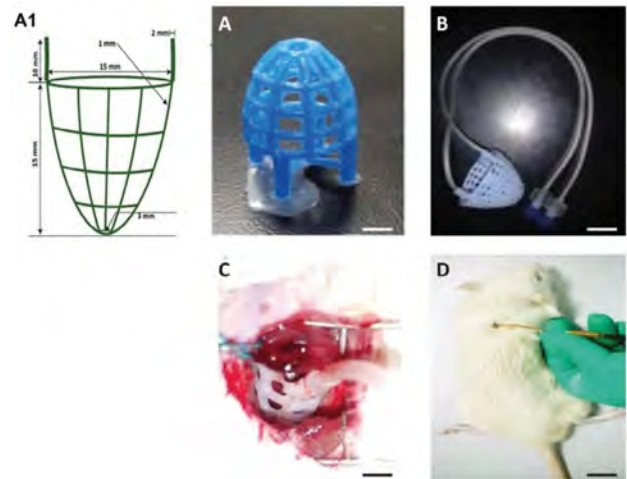


Figure 1. (A1) Dimensions of an ASD device in SD rats, (A) Silicon-based ASD device, (B) ASD connected to an implantable catheter, (C) ASD device implantation, (D) a catheter opening in the skin for BMSCs injection, scale bar 100 μ m.

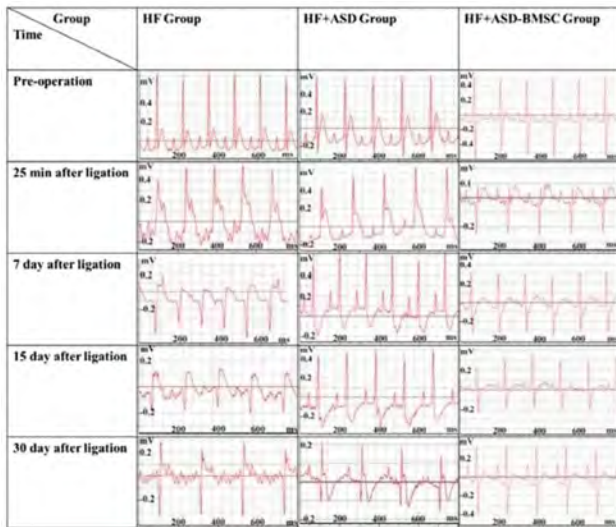


Figure 2. Electrocardiogram (ECG) observations for preoperative, 25-min, 7th, 15th, and 30th days after ligation of different treatment groups, HF, HF +ASD, HF + ASD-BMSC, n = 3.

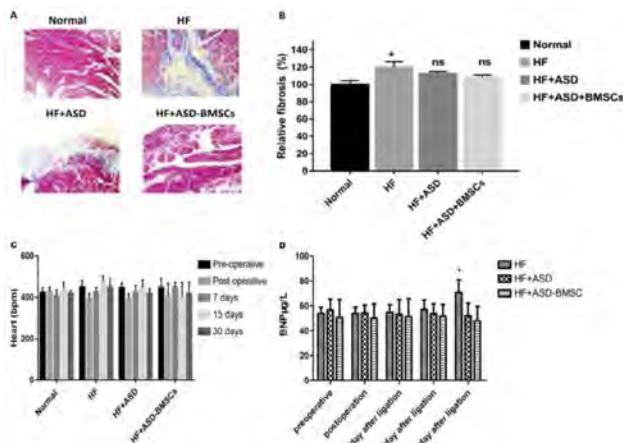


Figure 3. Histopathology of heart tissues, (a) Masson's trichrome staining of cardiac tissue and fibrosis mark-up on digitized slides, (b) quantification of fibrosis of heart tissues obtained from different treatment groups, n = 3. (c) Heart rate and (d) Plasma BNP level of preoperative, postoperative, 7th, 15th and 30th days of different treatment groups (*P < 0.05) HF vs. HF + ASD and HF vs. HF + ASD-BMSCs at 30 days, n = 3.

CARD21

Fontan Assist Device: Assessing FAD Effects during Exercise in Patients with Single Ventricle Anatomy

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Background: Patients with Fontan circulation suffer from a multitude of complications related to chronic low cardiac output and elevated central venous pressure. Due to the absence of an active pulmonary circuit pump, Fontan patients also experience low exercise capacity. We are working on a Fontan Assist Device: a small axial flow pump inserted in the Total Cavopulmonary Connection (TCPC). In a previous study, we examined the effect of a Fontan Assist Device (FAD) under various medications and observed how these combined treatments can improve patients' conditions. This study investigates how the FAD treatment can support Fontan patients during demanding exercise by examining the effect on hemodynamics.

Methods: A customized OD lumped parameter model of the Fontan circulation, programmed using Matlab Simulink, was utilized to simulate patient-specific hemodynamics. Three distinct clinical data stages (from the literature): resting, walking, and running were established to replicate the hemodynamic conditions of a single patient. The model was tuned to match the same hemodynamic condition and used as the baseline before treatments. For the FAD treatment simulation, two axial pumps inside the pulmonary arteries were added and run at 15000 RPM, 19500 RPM, and 24500 RPM at resting, walking, and running, respectively. Additionally, FAD treatment with diuretic simulation was achieved by reducing the total circulation volume in the simulation.

Results: In general, the simulation was able to closely replicate the clinical data available in the literature with only 0.8L/min higher maximum cardiac output compared to expected in the simulation. When FAD was activated in all three condition stages, the Fontan pressure decreased by ~1 mmHg while cardiac flow increased by 0.97 L/min during rest, 0.95 L/min during walking, and 0.84 L/min during running. By combining FAD treatment with diuretics, Fontan pressures were decreased by ~4-6 mmHg while maintaining or augmenting mean pulmonary artery pressures. Total cardiac output was augmented in FAD only as well as FAD + diuretic compared to baseline for all activity states. Such treatment can help alleviate the pressure on internal organs and improve overall cardiac flow, leading to a better quality of life for patients with Fontan circulation.

Conclusion: In conclusion, FAD treatment can be valuable in supporting Fontan patients for at rest as well as during exercise. When combined with diuretic medications, central venous pressure can be effectively reduced while maintaining an improvement in cardiac output at rest, walking, and running states. This would be expected to alleviate the hemodynamic burden of Fontan circulation and improve exercise capacity.

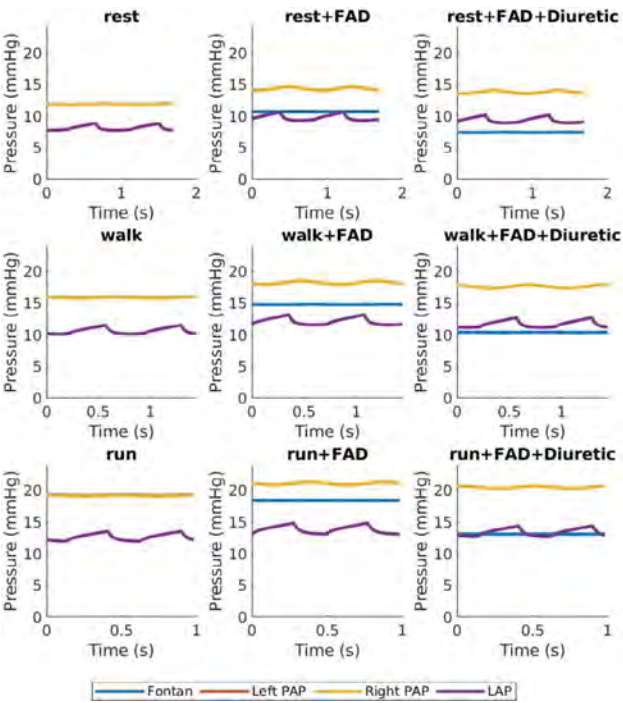


Figure 1. Pressure wave near Fontan region

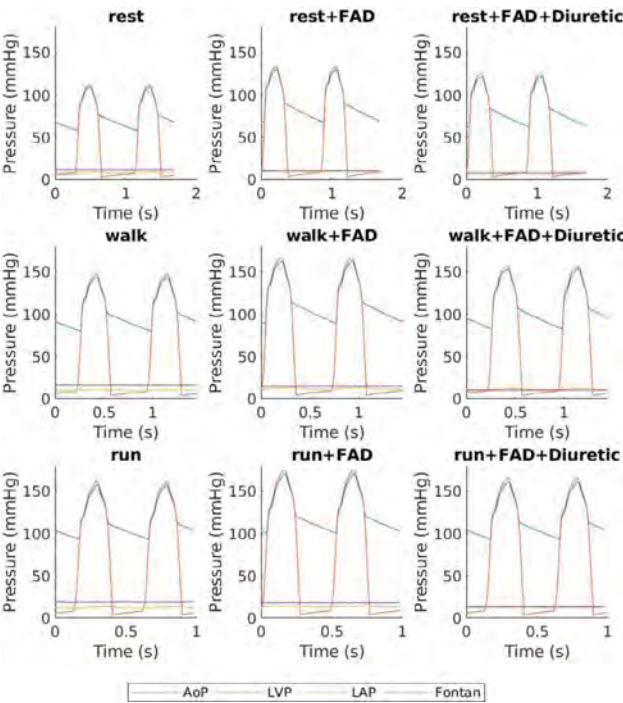


Figure 2. Pressure wave near Left Ventricle region

Table 1. Hemodynamic summary of all simulation trial

Name	Simulation					Literature				
	MCP/ FON TAN (mm Hg)	PAP (mm Hg)	MAP (mm Hg)	LAP (mm Hg)	CO (L/ min)	MCP/ FON TAN (mm Hg)	MAP (mm Hg)	LAP (mm Hg)	CO (L/ min)	
Rest	12	12	77	8	4.19	12	83	8	4.50	
Rest+ FAD	11	14	91	10	5.16					
Rest+ FAD+ Diuretic	7	14	85	9	4.97					
Walk	16	16	104	11	5.88	16	102	11	5.76	
Walk+ FAD	15	18	117	12	6.83					
Walk+ FAD+ Diuretic	10	18	110	12	6.64					
Run	19	19	117	13	7.85	19	106	13	7.02	
Run+ FAD	18	21	126	14	8.69					
Run+ FAD+ Diuretic	13	21	119	13	8.50					

CARD22

Effect of Left Ventricular Unloading on Heart-Lung Interactions During Mechanical Ventilation

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Background: Percutaneous ventricular assist devices (pVADs) are increasingly employed in cardiogenic shock despite limited understanding of their optimal use to improve clinical outcomes. Concomitant respiratory failure requiring mechanical ventilation is a particular challenge as both pVAD and ventilator impact cardiac loading states. This study aims to deepen understanding of heart-lung interactions arising from dual support with mechanical ventilation and pVAD to better inform management of shock patients.

Methods: A novel porcine model of titratable acute cardiogenic shock was used to quantify the effect of pVAD support on cardiac loading states with varied intrathoracic pressure. The cardiovascular response was assessed across positive end-expiratory pressure (PEEP) ramps in five animals and three states per animal, including health, health with pVAD, and pVAD-supported cardiogenic shock induced via coronary microembolization.

Results: This study incorporated ventricular volume measurements to augment standard metrics, allowing for assessment of pressure-volume loops and recreation of classic Frank-Starling curves (Figure 1). Increased intrathoracic pressure alters transmural pressure for cardiac and pulmonary vasculature to reduce venous return, while end-diastolic pressure also increased thereby indicating reduced ventricular compliance. Additionally, the corresponding effects on ventricular stroke volume yield a contiguous Frank-Starling curve and indicate either minimal effects on ventricular contractility or compensatory effects which allow for balance between ventricular elastance and arterial elastance with respect to ventricular preload. After the generation of cardiogenic shock, pVAD support minimized effects of PEEP in this diseased state compared to health (Figure 2). In particular, the effect on end-diastolic volume by PEEP was profoundly reduced for both ventricles in pVAD-supported shock compared to health, as were the reductions in RV compliance and pulmonary vascular resistance and compliance.

Conclusions: Application of advanced engineering for critical care has spurred development of new devices with profound impact. These devices alter intact physiology which complicates their use and demands deeper insight to maximize utility. Intriguingly, these results suggest that pVAD-supported patients in shock may better tolerate PEEP titration without added cardiopulmonary stress. This provides promise for management of patients with cardiopulmonary failure requiring simultaneous use of mechanical circulatory support and mechanical ventilation.

A) Left and B) right ventricular pressure-volume loops across PEEP ramps in health. Corresponding C) left and D) right ventricular Frank-Starling Curves.

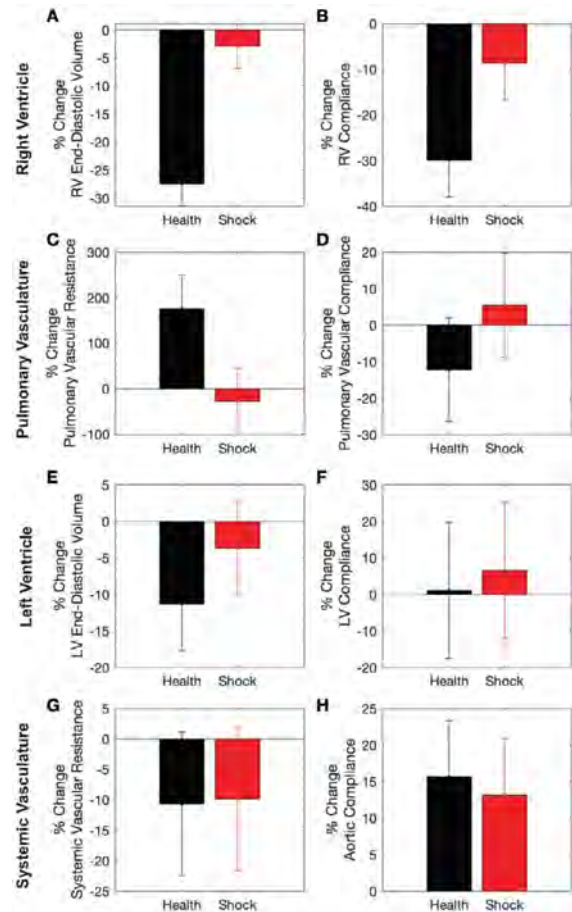


Figure 2. Cardiopulmonary Interactions with pVAD Support in Health and Shock

Effect of increased PEEP on pVAD-supported healthy heart and pVAD-supported cardiogenic shock, measured by change in right ventricular A) end-diastolic volume and B) compliance, pulmonary vascular C) resistance and D) compliance, left ventricular E) end-diastolic volume and F) compliance, and systemic vascular G) resistance and H) compliance.

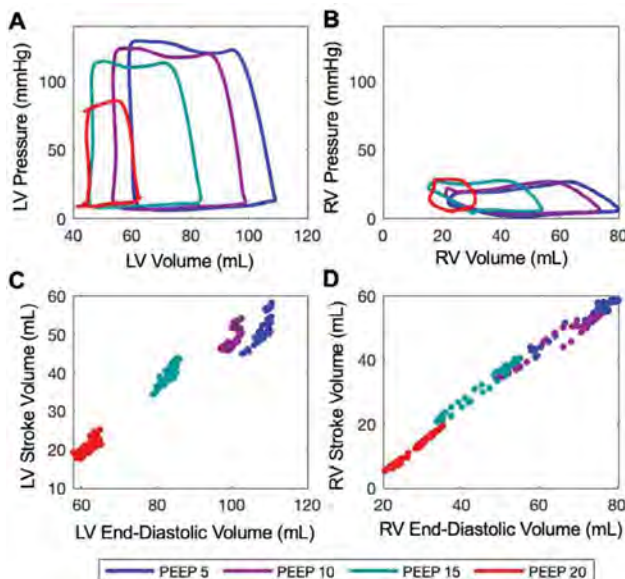


Figure 1. PEEP Impact on Ventricular Function

CARD23

Stopping micro-aspiration induced lung injury using pulsed electrical stimulation in intubated patients.

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Background: Pulmonary macro/micro aspiration of gastric contents puts One in 25 patients at risk of death due to early acute lung injury. This acute reflux is implicated in the pathogenesis of lung injury in intubated/ventilated patients. Anesthetic agents, sedatives and opiates relax lower esophageal sphincter (LES) leading to acute gastroesophageal reflux (GER). CDC guidelines recommend head elevation as a central strategy to mitigate this risk. Changing demographics of work force and constant need for education has been cited as reasons for lower compliance with this recommendation. We present an innovative electrical stimulation of LES to prevent GER and lung injury in intubated patients.

Methods: Polyurethane NoFlux tube was extruded on a 14 Fr mandrel and incorporated stainless steel ring electrodes that were used for stimulation at 5-15 mAmp, pulse width of 300 microsec, 5Hz rate for 30 min controlled by a micro-chip controller. Tube with electrodes were positioned under endoscopic guidance below the lowest cardiac margin (oro-esophageal). Extensive in-vitro tests were conducted to standardize pulse wave duration. Six Yorkshire pigs (3F: 3M) intubated and ventilated, in **supine** position underwent placement of 14 Fr NoFlux tube under direct endoscopic vision and electrodes were positioned within the lower esophageal sphincter (LES). Millar pressure transducer was placed within the LES for-pressure measurement with aim of obtaining >15 mm Hg pressure over the gastric pressure to assure closed status of LES.

Results: LES pressures: Pre-stimulation: 9±2 mm of Hg, post-stimulation: 31±4 mm of Hg, was obtained. No adverse events in terms of arrhythmia on ECG or diaphragmatic contractions observed for the duration of experiment. LES pressure increase post-stimulus was sustained for 90±30 minutes with gradual decrease. Abdomen was opened and extraluminal pacing leads were placed and experiment repeated as a control. Maximum LES pressure was observed at stimulation strength of 7 to 9 mAmp. Both extra and intra luminal strength corresponded within±1 mAmp for observed pressure differential. Gastric peristaltic waves were observed for effect on LES stimulation (baseline 3-4 cpm, increased to 5-6cpm), demonstrating modest increase. Total test duration 8hrs/animal. No histological damage seen on light microscopy in the lower 5 cm of esophagus at 100X magnification.

Conclusion: An esophageal pressure differential over gastric pressure can be maintained using a small electrical stimulus to maintain LES tone and prevent reflux of gastric contents. This has the potential to prevent and address one of the most important elements in the causation of acute lung injury in intubated patients.



PiroGon Device

CARD24

Prolonged Cardiopulmonary Bypass Time Induced Endothelial Dysfunction via Glypican 1 Shedding, Inflammation, and Matrix metalloproteinase 9 Activation in Patients Undergoing Cardiac Surgery

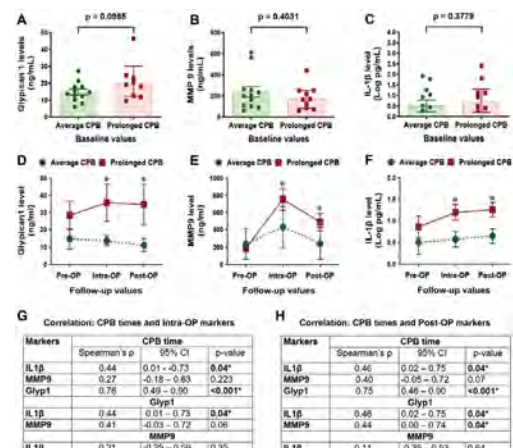
Shiyi Li¹, Katherine Nordick¹, Ivan Murrieta-Alvarez¹, Adel M. Hassan¹, Randall Parker Kirby¹, Camila Hochman-Mendez², Alexis Shafii¹, Todd Rosengart¹, Nandan Kumar Mondal¹, Kenneth Liao³; ¹Surgery, Baylor College of Medicine, Houston, Texas, United States, ²Regenerative Medicine Research,, Texas Heart Institute, Houston, Texas, United States

Background: Prolonged cardiopulmonary bypass (CPB) time (>180 min) during cardiac surgery is associated with worse postoperative outcomes and higher mortality. This association may be mediated by endothelial dysfunction, but the mechanisms by which CPB causes endothelial dysfunction remain unclear. Glypican1 (Glyp1), a key component of endothelial glycocalyx, may undergo proteolytic cleavage and shed into the plasma, leading to endothelial dysfunction. We tested the hypothesis that Glyp1 shedding is induced by CPB and results in endothelial dysfunction by evaluating the association of prolonged vs. average CPB time with plasma levels of Glyp1 and with matrix metalloproteinase 9 (MMP9) and pro-inflammatory cytokine interleukin 1 beta (IL1β).

Methods: Twenty-two patients undergoing cardiac surgical procedures were divided into two groups by CPB duration – (i) average CPB (<180 minutes, n=12) and (ii) prolonged CPB (>180 minutes, n=10). Pre-, intra- and post-operative blood samples were collected from each patient. Pre-OP samples were collected at admission. Intra-OP samples were drawn at the end of CPB. Post-PO samples were collected at discharge. Plasma levels of Glyp1, MMP9, and IL1β were measured in all samples.

Results: Pre-Op plasma levels of Glyp1, MMP9, and IL1β remained comparable between the average and prolonged CPB groups (Fig.A-C). Intra-OP Glyp1, MMP9, and IL1β were significantly elevated in the prolonged CPB group compared to the average CPB group. In the prolonged CPB group, at the time of discharge (Post-OP), the Glyp1 and IL1β levels remained as high as Intra-OP levels, but the MMP9 decreased compared to Intra-OP levels although it did not return to the baseline values (Fig.D-F). In the average CPB group, the Glyp1 and IL1β remained unchanged in all 3 time points and always remained significantly lower compared to the corresponding time points in the prolonged CPB group (Fig.D,F). However, the MMP9 levels in the normal CPB group spiked at Intra-OP but returned to the Pre-OP levels at the time of discharge. Correlation analysis indicated that prolonged CPB time was positively associated with both the intra-OP and post-OP IL1β, MMP9, and Glyp1 (Fig.G,H). Moreover, the Glyp1, MMP9, and IL1β were found to be positively associated with each other (Fig.G,H).

Conclusions: Prolonged CPB time triggered a systemic inflammatory response and MMP9 activation, leading to Glyp1 shedding, which might be responsible for endothelial dysfunction in this group of patients. Endothelial dysfunction is associated with worse post-operative outcomes and higher mortality rates after cardiac surgery. Glyp1 shedding can be used as a potential target to alleviate endothelial dysfunction and improve clinical outcomes in patients undergoing cardiac surgery.



PEDS1

A Novel Machine Learning Risk Model for Pediatric Patients Requiring a Ventricular Assist Device Between Listing for Transplant and Heart Transplant

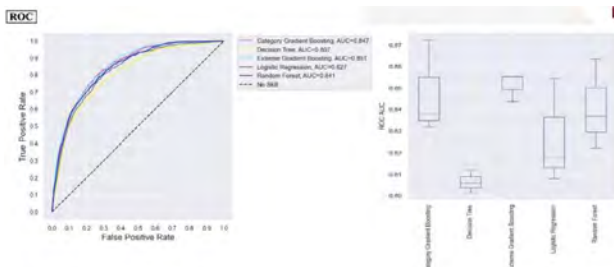
Zachary Brennan¹, Michael Bowdish¹, Dominic Emerson¹, David Ouyang¹, Joanna Chikwe¹, Jeffrey Jacobs²; ¹*Cedars Sinai Medical Center, Los Angeles, California, United States*, ²*University of Florida, Gainesville, Florida, United States*

Background: Machine Learning (ML) is an established technique for modeling associations in data and has shown value in modeling risk for various medical outcomes. Accurate prediction of pediatric patients requiring a Ventricular Assist Device (VAD) while on the waitlist, and the associated variables related to those predictions, could greatly assist clinicians in their decision making process surrounding pediatric patients requiring heart transplant.

Methods: STREAMLINE is an automated ML tool which can apply multiple ML algorithms (Random Forest, Logistic Regression, Decision Tree, Category Gradient Boosting, and Extreme Gradient Boosting) to suitable datasets. These algorithms assess complex relationships in datasets and create a model using “training” data, then use a “testing” dataset to assess accuracy of the model. Pre-transplant recipient data from the UNOS Database for pediatric heart transplant patients, meaning patients under 18 years of age, that did not have a VAD at listing and received a transplant between July 1 2003 and June 30 2023 were cleaned and entered into the ML tool. Both a training and testing dataset were used and three iterations of each model were created in order to best validate each model.

Results: 6,631 patients were included who had received a heart transplant over the twenty year period specified but did not have a VAD at listing; this dataset included over 380,000 unique datapoints to be utilized in modeling. The primary endpoint was whether a patient received a VAD at transplant or not. All models had a high Area Under the Curve (AUC), or ability to accurately predict VAD implant, between 0.807 and 0.851; Extreme Gradient Boosting had the highest at 0.851. Feature importance evaluation revealed that increased days on the waitlist, especially increased days in waitlist status 1A, congenital diagnosis, recipient medical condition at listing, prior cardiac surgery, lower serum albumin, prior transplant of any organ, inotropic support, ventilator requirement at listing, and lower initial age were among the most important features in the models predicting requirement of VAD prior to transplant.

Conclusion: Our models’ predictive ability are well above industry standards (AUC 0.6 to 0.7) for risk assessment, and above comparable models such as the STS Risk Calculator which has an AUC of 0.791 for Surgical Aortic Valve Replacement. These ML-based prediction models allow for increased understanding of pediatric patients who may require a VAD on the waitlist, including the ability to assess when they may require VAD after listing. The complex ML algorithms also allow us to understand some of the most common traits that influence the requirement of a VAD before transplant.



PEDS2

Breaking Tradition: The Bivalirudin Advantage in Pediatric Mechanical Circulatory Support

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Background: Utilization of bivalirudin, a direct thrombin inhibitor, in lieu of unfractionated heparin (UFH), is widely adopted in pediatric ventricular assist devices (VAD), yet its use and efficacy in extracorporeal membrane oxygenation (ECMO) remains uncertain. We have transitioned systemic anticoagulation to bivalirudin for all VAD and ECMO cases since 2017 & 2018, respectively. We evaluated bivalirudin’s safety profile compared to UFH on patients requiring mechanical circulatory support (MCS), both VAD and ECMO.

Methods: Single-center retrospective analysis over a 10-year period (2013-2023) reviewing patients receiving MCS. Patients were categorized as receiving either VAD or ECMO and further stratified based on anticoagulation type. Demographics, clinical characteristics & outcomes including device component changeouts, bleeding & thrombotic complications, survival to decannulation & discharge, were compared. Our hypothesis was that bivalirudin use improves survival while limiting bleeding complications. Analyses were performed using R version 4.2.2.

Results: Of 168 patients, 134 required ECMO and 34 VADs for a total of 189 MCS runs. The median (IQR) age of onset for ECMO was 5 (0.7, 24) months vs 108 (10, 180) months for VAD patients. Bivalirudin was used in 43/148 (29.1%) ECMO and 25/41 (62.5%) VADs. Common diagnoses for ECMO and VAD included congenital heart disease and cardiomyopathy, respectively. The most frequent mode of ECMO support was veno-arterial (114/148, 77%) vs veno-venous (27/148, 18.2%) vs 7/148 (4.7%) with both. Bivalirudin was utilized in 14/43 (32.6%) extracorporeal cardiopulmonary resuscitation cases vs. 49/105 (46.7%) UFH ECMO runs. In VAD patients, bivalirudin was associated with increased survival to decannulation or transplant (bivalirudin: 20/21, 95.2% vs UFH: 9/15, 60%, $p = 0.013$) and survival to discharge (bivalirudin: 18/21, 85.7% vs UFH: 7/15, 46.7%, $p = 0.025$). Compared to UFH, ECMO patients on bivalirudin were more likely to survive the hospitalization (OR 2.4, 95% CI 1.1-5.3, $p = 0.02$) and trended towards improved survival to decannulation or transplant (76.3% vs. 60.6%, OR 2.1 95% CI 0.9-5.1, $p = 0.09$). The number of ECMO patients on bivalirudin who never required a circuit component exchange was higher than UFH (bivalirudin: 30/43, 70% vs UFH: 56/105, 53%). Only one (2.6%) ECMO patient suffered a hemorrhagic stroke on bivalirudin compared to 15 (15.2%) of those on UFH.

Conclusion: Compared to UFH, bivalirudin use improved survival to discharge rate for both ECMO and VAD patients. Among VAD patients, bivalirudin showed improved survival to decannulation or transplant. Importantly, both VAD and ECMO patients experienced fewer bleeding complications, including hemorrhagic stroke. While bivalirudin’s superiority vs UFH in VADs has been shown, we herein demonstrate its advantages in our ECMO population. Further validation through larger, multi-center, randomized trials is warranted to solidify these findings.

Table 1. Baseline Characteristics. Results are displayed in median (IQR) and N (%). BSA, body surface area; CHD, congenital heart disease; ECMO, extracorporeal membrane oxygenation; MCS, mechanical circulatory support; HTN, hypertension. VAD, ventricular assist device.

Characteristic	ECMO			VAD		
	Total N=134	Bivalirudin N=36	Heparin N=98	Total N=34	Bivalirudin N=23	Heparin N=11
Age at MCS start (months)	5 (0.7, 24.0)	7.5 (2.6, 36.0)	4.0 (0.7, 24.0)	108.0 (10.0, 180.0)	108.0 (15.0, 192.0)	108.0 (14.0, 168.0)
Weight (kg)	5.8 (3.4, 13.0)	7.4 (4.0, 13.4)	4.6 (3.3, 12.2)	38.0 (8.8, 61.8)	42.0 (10.6, 70.0)	27.0 (10.3, 49.5)
Sex						
female	70 (52.2%)	17 (47.2%)	53 (54.1%)	11 (32.4%)	9 (39.1%)	2 (18.2%)
male	64 (47.8%)	19 (52.8%)	45 (45.9%)	23 (67.6%)	14 (60.9%)	9 (81.8%)
Race						
African American	27 (20.3%)	7 (19.4%)	20 (20.6%)	7 (20.6%)	6 (26.1%)	1 (9.1%)
Caucasian	92 (69.2%)	23 (63.9%)	69 (71.1%)	25 (73.5%)	16 (69.6%)	9 (81.8%)
Other	15 (11.2%)	6 (16.7%)	9 (9.2%)	2 (5.9%)	1 (4.3%)	1 (9.1%)
BSA	0.3 (0.2, 0.6)	0.4 (0.2, 0.6)	0.3 (0.3, 0.6)	1.2 (0.5, 1.7)	1.4 (0.5, 1.7)	1.0 (0.5, 1.6)
Primary Diagnosis						
CHD	82 (61.2%)	21 (58.3%)	61 (62.2%)	11 (32.4%)	7 (30.4%)	4 (36.4%)
Biventricular	57 (42.5%)	14 (38.9%)	43 (43.9%)	10 (29.4%)	6 (26.1%)	4 (36.4%)
Single ventricle	25 (18.7%)	7 (19.4%)	18 (18.4%)	1 (2.9%)	1 (4.3%)	0 (0.0%)
Non-CHD	52 (38.8%)	15 (41.7%)	37 (37.8%)	23 (67.6%)	16 (69.6%)	7 (63.6%)
Arrhythmia	3 (2.2%)	1 (2.8%)	2 (2.0%)	1 (2.9%)	1 (4.3%)	0 (0.0%)
Cardiomyopathy	4 (3.0%)	1 (2.8%)	3 (3.1%)	18 (52.9%)	14 (60.9%)	4 (36.4%)
Myocarditis	3 (2.2%)	1 (2.8%)	2 (2.0%)	2 (5.9%)	1 (4.3%)	1 (9.1%)
Other	14 (10.4%)	3 (8.3%)	11 (11.2%)	1 (2.9%)	0 (0.0%)	1 (9.1%)
Pulmonary HTN	11 (8.2%)	4 (11.1%)	7 (7.1%)	1 (2.9%)	0 (0.0%)	1 (9.1%)
Respiratory	17 (12.7%)	5 (13.9%)	12 (12.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table 2. Comparative MCS outcomes by primary mode of anticoagulation. Results are displayed in N (%). Odds ratio (OR) and 95% confidence interval (CI) from logistic regression models comparing mode of anticoagulation. ECMO, extracorporeal membrane oxygenation; MCS, mechanical circulatory support; Tx, transplant; VAD, ventricular assist device.

Outcome	ECMO N=137				p-value	VAD N=36			p-value
	Bivalirudin N=38	Heparin N=99	OR (95% CI)	Heparin N=15		Bivalirudin N=21			
Any Stroke	6 (15.8%)	17 (17.2%)	0.9 (0.3, 2.4)	0.85	2 (13.3%)	5 (23.8%)	0.7		
Hemorrhagic Stroke	1 (2.6%)	15 (15.2%)	-		1 (6.7%)	0 (0.0%)	0.4		
Ischemic Stroke	6 (15.8%)	2 (2.0%)	-		2 (13.3%)	5 (23.8%)	0.7		
Survival to Decannulation/Tx	29 (76.3%)	60 (60.6%)	2.1 (0.9, 5.1)	0.09	9 (60.0%)	20 (95.2%)	0.013		
Survival to Discharge	24 (63.2%)	41 (41.4%)	2.4 (1.1, 5.3)	0.02	7 (46.7%)	18 (85.7%)	0.025		

PEDS3

Clinical Characteristics and Outcomes of Pediatric Destination Ventricular Assist Devices

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Background: Ventricular Assist Devices (VADs) are used in the management of pediatric advanced heart failure with excellent survival with most implanted with a bridge-to-transplant (BTT) strategy. Lifelong "Destination" Therapy (DT) VADs are increasingly utilized in adults not suitable for cardiac transplant, however few data exist for pediatric patients. We describe the clinical characteristics and outcomes of pediatric DT patients in the ACTION registry.

Methods: Retrospective cohort analysis of pediatric VAD implants from January 2012 - August 2023 was performed. Baseline demographics, support type, adverse events, and clinical outcomes were assessed.

Results: Twenty-seven patients underwent DT VAD; 2% of all implants. Median age at implant was 18.7 years, median weight 61.3 kg. Most common underlying diagnoses were dilated cardiomyopathy/myocarditis (15/27, 55.6%) and congenital heart disease (8/27, 29.6%), including 5 with univentricular circulation. Most were Intermacs Profile 2 (51.9%) or 3 (25.9%) at implant; 3 (11.1%) were on ECMO. Most (74.1%) were supported with implantable continuous flow devices, median support duration 684 days (range 16 - 1824) compared to BTT cohort of 78 days (0 - 3695). Nineteen (70.3%) remain alive on device. Compared to contemporary BTT patients, there were no statistically significant differences in rates of neurologic dysfunction, bleeding, or major infection.

Conclusion: Pediatric DT patients remain a small proportion of children supported on device therapy, limited mostly to older and larger patients who can accommodate a dischargeable device. Pediatric DT patients may be supported for several years after implant with favorable adverse event outcomes.

	BTT (n = 763)	DT (n = 27)	P Values
Clinical Characteristics			
Age in years	3.16	18.7	<0.001
Weight in kg	12.9 (2.4 - 154)	61.3 (4.4 - 122.7)	<0.001
BSA in meters ²	0.581 (0.17 - 2.8)	1.7 (0.26 - 2.41)	<0.001
Gender - Female	330 (43.3%)	8 (29.6%)	0.15
Clinical Outcomes			
Alive on device	65 (8.52%)	19 (70.3%)	
Deceased on device	74 (9.70%)	6 (22.2%)	
Transplanted, alive	572 (75%)	1 (50.4%)	<0.001
Ventricular recovery	22 (2.8%)	0 (0.0%)	
Adverse Events			
	(DDs=104503)	(DDs = 19420)	
Neurological Dysfunction	18.9	19.8	0.76
Bleeding (any)	19.4	27.7	0.3
Major infection	30.8	35.8	0.19

Table 1 - Baseline characteristics, clinic outcomes (reported as number of patients & percent of total) and major adverse events (reported as number of events per 10000 device days) compared between BTT and DT registry cohorts.

PEDS4

Variation in Medication Regimen for Children Discharged on a VAD in the United States

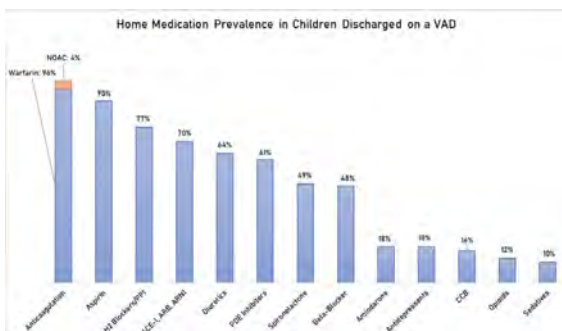
Amir Mehdizadeh-Shrifi¹, Muhammad Faateh¹, Kevin Kulshrestha¹, Chet Villa², Tanya Perry², Spencer Hogue¹, Katrina Fields², Angela Lorts², David Morales¹; ¹Cardiothoracic Surgery, Heart Institute, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, OH, Cincinnati, Ohio, United States, ²Pediatrics, Heart Institute, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, OH, Cincinnati, Ohio, United States

Background: As utilization & management of pediatric ventricular assist devices (VADs) have progressed, an increasing number of children are now being discharged on a VAD. However, great variation in pharmacotherapy at discharge exists amongst programs. The authors sought to describe modern trends in medication usage in children discharged home on a VAD.

Methods: The Pediatric Health Information System database was queried for pediatric (<18 years) VAD utilization from 2004-2023. Dischargeable VADs were identified by procedural ICD-9/10 codes & by excluding patients who underwent heart transplantation, VAD explantation, or inpatient/hospice discharge. Center Volume was calculated by years from start to present of each participating institution and divided by total number of VAD utilization. (LV: <3, MV: 3-6, HV >7).

Results: 285 children were discharged home while on a VAD. The indications for VAD were cardiomyopathy (n=228, 80%) and congenital heart disease (n=36, 13%). 13% (n=37) of patients were discharged from LV centers, 54% (n=153) MV and 33% (n=95) HV centers. The median number of discharge medications (D/C meds) was 8 [IQR 6-10]. Differences in median D/C meds were found based on patient sex (Female: 10 [6-11] vs. Male: 8 [6-10], p 0.023), age group (Age 15-17: 9 [7-12] vs. Age 9-11: 7 [5-9], p <0.001), and center volume (LV: 9 [7-10] vs. MV: 8 [5-9] vs. HV: 7 [6-9], p<0.001). Post-operative LOS was 38 [26-59] days. Patients discharged with <25th Percentile LOS were on 7 [5-9] medications vs. >75th Percentile 9 [6-10], p 0.01. Black and Non-White Hispanic patients had higher median D/C meds (Bl: 8 [6-10] vs. W: 7 [5-9], p 0.03, Hisp. Non-White: 8 [7-10] vs. Non-Hisp. White: 7 [5-9], p 0.001). Indication did not effect D/C meds. 48% (n=136) of patients were prescribed a beta-blocker. The majority received Metoprolol (n=67), followed by Carvedilol (n=59). 16% (n=45) were treated with dihydropyridine calcium channel blockers and 64% (n=181) were discharged with a loop diuretic. 70% (n=198) received treatment with a renin-angiotensin-aldosterone system inhibitor. Furthermore, 47% (n=133) also had Sildenafil and 14% (n=40) Tadalafil in their discharge regimen. The majority underwent antiplatelet therapy with Aspirin (n=254, 90%) and anticoagulation with Warfarin (n=266; 94%). Antidepressants were prescribed to 18% (n=52), sedatives to 10% (n=27) and opioid analgesics to 12% (n=34). Acid-suppressing drugs were given to 77% (n=217).

Conclusion: In the United States, most children on a VAD are discharged with eight daily medications. While there is great variation in pediatric VAD pharmacotherapy, certain heart failure, anti-coagulation and -platelet drugs have been universally adopted. Since discharging children on VAD support continues to increase, an opportunity to collaborate and determine best practice for discharge medications regimen exists.



Home Medication Prevalence in Children Discharged on a VAD

PEDS5

A New Paradigm for Management of Single Ventricle Fontan Circulation with High Redundancy Mechanical Circulatory Support

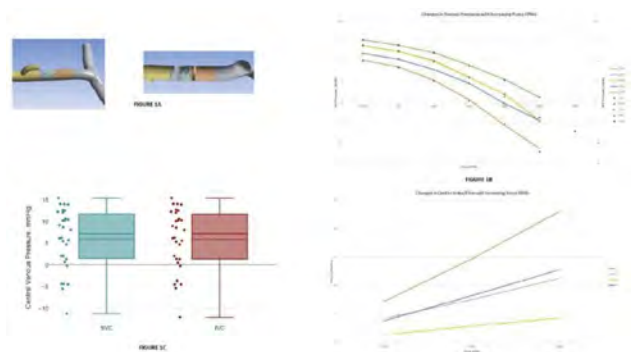
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Background: Current Fontan Total Cavopulmonary Connection (TCPC) have hemodynamic inefficiencies and are very challenging to support mechanically. We have previously shown that a new configuration of Fontan, the Convergent Cavopulmonary Connection (CCPC) has significantly improved hepatic flow distribution (HFD) and % subphysiologic wall shear stress (%WSS) compared to TCPC and is also easily supported with a single mechanical circulatory support (MCS) device with increase flow (CI) and symmetrical decompression of the central venous pressure (CVP) in both the SVC and IVC. Non Obstructive Venous Assist Device (NOVAD) is an interposition MCS device with a hollow core impeller designed to specifically replace the extracardiac Fontan conduit. It can provide flows of up to 3-5L/min across a 15mmHg pressure differential at less than 3000RPMs. The static pressure drop of <3mmHg across the pump creates a highly redundant system. This study aims to determine the hemodynamic improvements in the Fontan by addition of the NOVAD to CCPC Fontan circuit.

Methods: 5 patient derived cardiac MRI data were segmented to create patients specific CCPC models. The NOVAD pump was virtually placed in the common limb of the CCPC (Figure 1A) as an interposition graft. CFD analysis was used to assess the changes in Fontan Hemodynamics (CVP & CI) with increasing pump speeds. Repeat measure ANOVA was used to assess changes in CVP and CI with increasing pump support.

Results: The NOVAD could be successfully incorporated in the common limb of the CCPC in all 5 patients. Increasing pump speeds led to significant decrease in CVP (P<0.001) (Figure 1B). The pressure drop in the SVC and IVC were symmetrical for all cases (Figure 1B&C). Increasing pump speeds also led to significant increase in CI (P=0.009) in all models (Figure 1D).

Conclusion: Fontan circulation using CCPC configuration can be easily supported mechanically using a single pump. Increasing NOVAD pump support decompress CVP symmetrically in both the SVC and IVC and leads to progressively higher CI. By simplifying the Fontan circulation into a single inflow and single outflow CCPC configuration can provide an optimal solution to Fontan failure by providing both a more efficient Fontan circulation at baseline and can also be easily supported with a single NOVAD subpulmonary device.



PEDS6

Chronic In Vivo Test of the Penn State Child VAD

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Purpose: There is a need for long-term implantable mechanical circulatory devices for pediatric patients between 10 and 30 kg. Our group has developed a centrifugal, continuous flow left ventricular assist device for children 10 to 30 kg (BSA 0.5 to 1.2 m², 1 to 8 years of age). The objective of this study was to evaluate long-term biocompatibility in a chronic animal study.

Methods: The Penn State Child VAD was implanted into a 37.6 kg male lamb via a left lateral thoracotomy. The 8 mm diameter inlet cannula is fixed to the pump housing and was installed in the ventricular apex. The 8 mm diameter outlet graft was anastomosed end-to-side to the descending aorta. The pump was initially started at 6500 rpm and remained at that speed for the initial post-operative period. The speed was ramped to 7000 rpm on post-operative day (POD) 4 to increase pump output and was unchanged for the remainder of the study. Anticoagulation was controlled by unfractionated heparin targeting 1.5x normal aPTT. Hematologic evaluation was monitored approximately twice a week throughout the study. The animal was electively euthanized on POD 26 and a necropsy was performed immediately.

Results: The pump delivered an estimated flow of 0.5-1.0 L/min, consuming 1.1 W of power immediately post-operatively until the pump speed was increased on POD 4 increasing flow to an estimated 1.0-1.5 L/min, and power to 1.6 W, where it remained for the duration of the study. Hematocrit remained stable at 31 ± 1%. aPTT was 32 sec pre-operatively and after fluctuating early in the study stabilized to 53 ± 5 sec. The percentage of high molecular weight von Willebrand factor decreased post-operatively to 20 ± 2% from pre-operative values (31 ± 1%) but remained normal. Plasma hemoglobin values remained low during the post-operative period (1.4 ± 1.5 mg/dL). Inspection of the pump upon removal from the animal revealed a fibrin deposit between the outer surface of the pump rotor and inner surface of the pump housing. The histological indicators of the deposit were most consistent with an antemortem thrombus; however, the chronicity of the thrombus was not able to be determined and there was no gross or histological evidence of thrombus formation within other regions of the pump or the cardiovascular system of the animal. Additionally, there was no significant increase in pump power during the duration of the study and the liver and kidneys showed no signs of thromboembolism or other abnormalities.

Summary: This study was the first chronic in vivo study with the Penn State Child VAD. The pump provided adequate circulatory support with no adverse events.

PEDS7

A Minimally Invasive Infant LVAD Achieves 96 hr Ambulatory Total LV Support in Lambs

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Background: Our goal is to develop a minimally invasive, reliable LVAD for infants.

Methods: The enabling technology of this LVAD system is a transapical to aorta double lumen cannula (TAA DLC), which is inserted from the apex through the LV into the aorta (Fig A). When connected with a blood pump, the TAA DLC withdraws blood from the LV and delivers blood to the aorta to achieve total LV unloading. The TAA DLC was made by polyurethane dip molding with memory alloy wire reinforcement. The TAA DLC prototype (25/13 Fr) was tested in a mock loop with 37% glycerin and in 4 week old lambs for 96 hrs. In the lamb study, the heart apex was exposed via a small (3 cm) anterior left thoracotomy. A vascular graft was sewn onto the apex, and the TAA DLC was inserted into the LV-aorta through a 0.5 cm incision on the apex within the graft. The TAA DLC was then connected to the extracorporeal CentriMag™ blood pump via 1/4" tubing (Fig B). The TAA DLC was secured by suturing it to the vascular graft and chest wall during thoracotomy closure.

Results: The 25/13 Fr TAA DLC achieved maximal >3 L/min flow in the mock loop. In lambs (12.7-17 kg, n=5), all TAA DLCs were easily inserted/ properly deployed within 1 min, and the entire installation procedure was completed in less than 30 min. Within 2 hours after moving to ICU, all 5 lambs were weaned from anesthesia and ate/drank normally with ambulation throughout 96 hrs (Fig C). The TAA DLC was well secured through the apex-vascular graft, and the LVAD flow was consistently about 2 L/min. At 96 hrs, hemoglobin was similar to baseline levels (Table) and free hemoglobin level was normal (<5 mg/dl). All other blood parameters were in physiological range at 96 hrs (Table), showing normal liver and kidney function. At necropsy, no TAA DLC thrombosis and no valve/ myocardial damage was present.

Conclusions: Our 25/13 Fr TAA DLC-based infant LVAD system is characterized by quick, minimally invasive installation, total LV support, and great hemocompatibility, showing great promise for future clinical application.

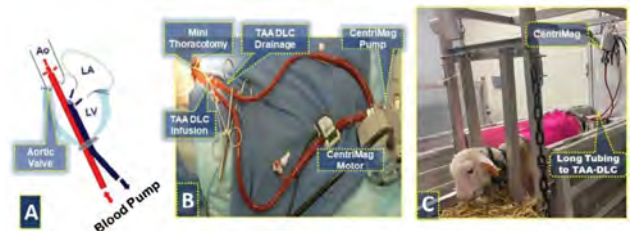


Figure 1. A. TAA DLC withdraws from LV and pumps to ascending aorta. Abbreviations: LV: left ventricle, LA: left atrium, Ao: aorta. **B.** The TAA DLC-based LVAD system. **C.** Lamb on the TAA DLC-based LVAD system with normal eating/drinking and ambulation.

Table 1. TAA DLC-Based LVAD: Lamb Study Blood Work Results

N=5	Baseline	96 hr
WBC (10 ³ /uL)	6.0±1.28	8.2±2.01
PLT (10 ³ /uL)	904±224	490±114*
AST (IU/L)	66±8.5	97±37.7
ALT (IU/L)	9±1.9	32±15.2*
BUN (mg/dL)	13±2.3	6±1.9*
CR (mg/dL)	0.7±0.11	0.3±0*
HgB (g/dL)	10.1±0.71	9.1±0.1
fHgb (mg/dL)	9.1±2.91	2.9±1.36*

WBC: white blood cell counts, PLT: platelets, AST: aspartate aminotransferase, ALT: alanine transaminase, BUN: blood urea nitrogen, CR: creatinine, fHgb: free hemoglobin

PEDS8

Novel Stabilization Of A Heartmate 3 Atrial Cannulated Ventricular Assist Device In A Fontan Patient

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Patients with single ventricle physiology and Fontan palliation are a growing subset of patients given overall improved life expectancy. Ventricular assist device (VAD) implantation for this population has been described however the variability in age, size, and anatomy can present challenges to successful VAD support. These patients may have long wait-list times due to antibody sensitization. Intracorporeal devices are favorable support strategies due to their overall adverse event profiles along with the potential for discharge and improved quality of life. Both atrial and ventricular inflow cannulation strategies have been reported using intracorporeal devices with various techniques to externally stabilize such devices with sutures to the chest wall when placed in the atrial position. This type of device pexy to the right sided ribs prevents compression of the right atrium especially with in the larger HeartMate 3 (HM3) device in the atrial position.

We describe a case of HeartMate 3 atrial cannulation of a Fontan patient using a novel internal stabilization technique with a GoreTex scaffolding unit in the right atrium. The scaffolding consisted of two fenestrated pant legs of a 20 mm ringed GoreTex graft, with an additional non-ringed proximal 22 mm GoreTex graft anastomosed to the pant leg construct that connected to the HM3 inflow cannula. This fenestrated scaffolding allowed for unobstructed pulmonary venous return to empty through either the HM3 inflow or the systemic tricuspid valve. This technique also served to prevent suctioning of a severely prolapsed tricuspid valve leaflet into the HM3 inflow. The entire apparatus was connected the HM3 inflow which was adhered to a sewing ring placed in the right atrial free wall. With this configuration, the patient had VAD flows of 4.5 L/min (Cardiac Index of 3.5 L/min/min²) at 5300 RPM. A 4mm fenestration was made in the Fontan conduit to help promote VAD filling. Following chest closure, the atrial pressure was 3, Fontan pressure of 11 mm of Hg. He was maintained on inhaled nitric oxide and low dose infusion of epoprostenol, later transitioned to tadalafil. He was extubated on POD 1 and remained inpatient for management of chronic ascites and ongoing de-sensitization therapy while listed Status 1A for heart transplant. He had non-sustained runs of atrial tachycardia and premature atrial contractions which was hemodynamically insignificant and did not affect flow of the device. He was supported on the device for 56 days without any complications on an anticoagulation regimen of coumadin and aspirin. This technique allowed for reliable support with no suction events, but the scaffolding could have contributed to some atrial ectopy albeit well tolerated. He underwent orthotopic bicaval heart transplantation with a prolonged postoperative course complicated by diastolic dysfunction, recurring ascites and chylous effusions. He was discharged on POD 56 and remains outpatient without further complications.



Figure 1A: Chest Radiograph of atrial cannulation with a HeartMate-3. B: HeartMate-3 pump position over right atrium with no clots seen around Gore-Tex scaffolding. C: 3-Dimensional reconstruction of HeartMate-3 pump from CT imaging

PEDS9

Multiple Run Pediatric ECMO Support And Futility. What Are The Limits?

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Background: Mortality rates are high in repeated extracorporeal membrane oxygenation (ECMO) runs. Re-deployments are frequently discussed in everyday clinical care. Since studies are scarce and those existing describe differing results, we aim to investigate predictors of mortality in pediatric patients undergoing multiple ECMO runs.

Methods: Clinical data from a single pediatric center was retrospectively analyzed. Patients who received more than one ECMO run between January 2010 and July 2023 were included.

Results: A total of 560 patients underwent 654 ECMO runs. Of those, 70 patients (13%) required multiple ECMO deployments accounting for 165 ECMO runs. The median age at first ECMO initiation was 24.3 (7-132) days. The cohort comprised of 36 neonates, 24 infants and 10 children between 1 and 16 years. Most patients had congenital heart disease (n=62, 89%) while 3 (4%) had myocarditis, 1 (1%) dilated cardiomyopathy and 4 (6%) non-cardiac diseases. A total of 63 patients (90%) underwent cardiac surgery and 50 patients (71%) had at least one ECMO initiation under cardiopulmonary resuscitation (ECPR) but there were no significant differences in outcome.

A total of 56 patients (80%) died before discharge. Of the 14 patients discharged alive, 6 died a median of 177 (31-365) days after discharge resulting in a long-term mortality of 89%; 8 (11%) patients were still alive at long-term follow-up a median of 1.6 (1.0-3.9) years after hospital discharge. A total of 54 patients (77%) had brain injuries. Seven of the eight long-term survivors had neurodevelopmental (ND) evaluations a median of 1.1 (0.5-2.1) years after the last ECMO run. Only two survivors of the overall cohort (3%) had a normal ND follow-up. In univariate analysis, duration of the first ECMO run (OR 2.63, 1.08-7.96), total duration on ECMO (OR 4.72, 1.29-23.54), brain injury at any time (OR 15.30, 3.05-115.49), need for renal replacement therapy (OR 4.79, 1.06-25.58) as well as highest lactate within the first 24 hours both during the first (OR 4.90, 1.31-23.91) and second ECMO run (OR 5.10, 1.35-29.48) were significant predictors for long-term mortality. All of the 22 patients (31%) who suffered brain injury before the second run died. The frequency of multiple run ECMOs increased from an average of 4 patients per year in the first half of the study period 2010-2016, accounting for 10% of all patients undergoing ECMO support to 6.5 patients per year and 15% of overall patients in the second half.

Conclusion: Pediatric patients with multiple ECMO runs have high mortality rates, and ND outcomes are compromised in almost all survivors. Careful consideration and discussion of risks and benefits should occur before considering a second ECMO run. Given all patients in our cohort with brain injury prior to second ECMO run died, absence brain injury should be considered as criteria for further ECMO runs.

PEDS10

Computational and *In Vitro* Flow Path Analysis for Pediatric Multi-Blood Pump with Dual Activation

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Background: Mechanical circulatory support (MCS) devices such as ventricular assist devices (VADs) have seen increasing adoption for pediatric patients with end-stage heart failure (HF). However, the clinical state of the art for pediatric VADs lags behind adult treatments, negatively impacting patient outcomes. To address this need, we are developing a novel, double-blood pump VAD that integrates an axial and centrifugal pump within one housing. The axial pump is utilized for initial circulatory assistance, then an internal activation mechanism triggers the centrifugal pump in line with the axial pump to increase pressure-flow performance and match patient growth cycles.

Methods: Here, we focused on the configuration, design, and improvement of the device flow paths through computational analysis and hydraulic testing, leveraging previously validated pump designs. Two turbulence models (k- ϵ and SST) were used to computationally analyze the flow paths, estimating pressure-flow generation, fluid scalar stresses, and blood damage levels. Device performance was iteratively improved through a prioritized design improvement process. Shaft-drive *in vitro* flow path prototypes were then tested using a water-glycerol analog solution. Hydraulic performance data was compared to computational predictions using non-dimensionalized regression analyses.

Results: The final flow path designs met hydraulic performance benchmarks using k- ϵ . Average shear stress, blood damage indices, and platelet activation indices were below 425 Pa and 2%, respectively. Blood shear stress levels, however, exceeded 425 Pa along the leading edge of blade tip clearances; this was expected based on previous analyses of the pump designs. Hydraulic tests correlated well with SST predictions; experimental results averaged 4.5% deviation for the complex, combined flow path. It would be necessary to increase pump speeds to provide sufficient pressure generation at higher flow rates.

Conclusion: There is a pressing need to innovate a novel long-term MCS device for pediatric HF patients. To address this need, we are developing a novel, double-blood pump, magnetically levitated, adaptable pediatric VAD that can provide long-term support across the pediatric age range. We developed a design configuration for the novel double-blood pump VAD, iteratively improved flow path geometries through CFD and a prioritized design improvement process, and validated simulation results through *in vitro* testing. The final geometry met design requirements in k- ϵ simulations; pressure-flow performance and flow path blood damage metrics fell within design targets. Experimental testing correlated well with SST model predictions, validating computational modeling of the device flow paths, with the ability to meet performance benchmarks at pump speeds exceeding original operational limits. These findings establish a strong foundation for the future development of the Drexel Double-Dragon VAD.

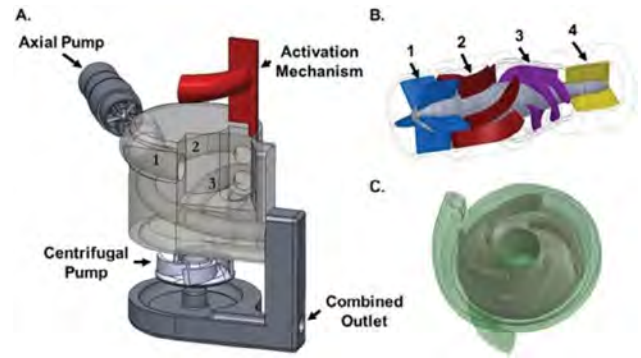


Figure 1. Drexel Double-Dragon VAD - Series Design. A: Exploded view of the Drexel Double-Dragon VAD - Series Design (sections of the device are rendered transparent for visibility). 1- Combined flow path leading into activation mechanism. 2- Axial-only bypass flow path. 3- Combined flow path leading from activation mechanism to inlet of centrifugal pump. **B:** Diagram of axial pump in housing. 1- Flow straightener blades. 2- Stationary diffuser blades. 3- Rotating impeller section. 4- Stationary inducer blades. **C:** Diagram of centrifugal pump in housing.

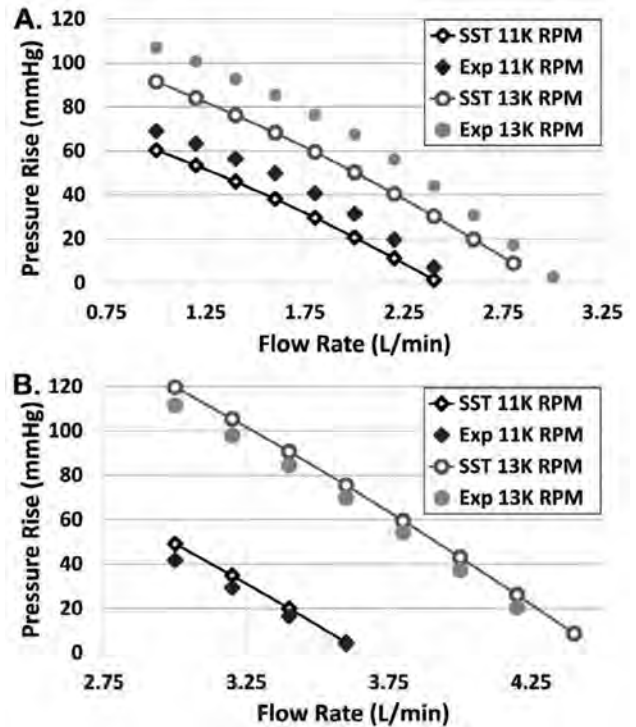


Figure 2. Experimental vs. computational results for the axial-only flow path (A) and the combined flow path (B) at two selected rotational speeds. Experimental and SST simulation results are illustrated.

PULM1

Extracorporeal Membranous Oxygenation Associated with Tracheal Procedures: an ELSO Database Analysis

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Background: Extracorporeal Membrane Oxygenation (ECMO) use has shown significant growth over the last decade following the improvement in technology and management. ECMO use was previously limited to supportive care in respiratory/circulatory failure, but recently has expanded to intraoperative support for complicated cases in lieu of cardiopulmonary bypass. Tracheal procedure is an application for which ECMO could be warranted to secure airway management.

Methods: The Extracorporeal Life Support Organization registry was queried for patients 18 years and older who were treated with ECMO in 2010-2022 during the same admission with types of tracheal procedures. Trends in the number of ECMO runs and survival over time were examined. Tracheal procedures were divided into surgical procedure and bronchoscopic procedure groups, and the survival rate was analyzed for each procedural type. Similarly, results were analyzed for each primary diagnosis group. Multivariable analysis was performed to detect risk factors for in-hospital mortality.

Results: Two-hundred and sixty-nine patients met the inclusion criteria (64 surgical procedures and 205 bronchoscopic procedures), and 173 patients (64.3%) survived to discharge. During the study period, the number of ECMO dramatically increased from 8 in 2010-2016 vs 261 in 2017-2022. Among the surgical procedures, tracheal resection was most commonly performed (30 patients; 46.9%) and was associated with a high survival rate to discharge (26/30; 86.7%; Table 1). On the other hand, surgical airway injury repair under ECMO was associated with poor survival (6/13; 46.2%). In bronchoscopic procedure, dilation (n=19), tracheal stent (n=71), bronchial stent (n=46), tumor excision (n=9), and mass destruction (n=60) were performed with reasonable survival rate (129/205; 62.9%). The distribution of the primary diagnosis is shown in Figure 1. While bronchoscopic procedures for COVID-related status were associated with a low survival rate (19/39; 48.7%), surgical procedures for malignancy had a high survival rate (10/11, 90.9%). Surgical site bleeding was seen in 35 patients (13.0%) and was associated with worse survival (42.9%; p=0.007; Table 2). Multivariable analysis identified older age (Odds ratio [OR] 1.04/year-old; p=0.002), longer ECMO duration (OR 1.01/day; p=0.030), lower PF ratio (OR 0.996; p=0.017), and venoarterial mode (OR 3.07; p=0.019) as independent risk factors for in-hospital mortality. **Conclusions:** ECMO associated with tracheal procedures was rare, but its use has increased over time. While the indication is limited, tracheal procedures can be safely performed with the support of ECMO in selected cases.

Table 1. Case Number and Survival Rate for Surgical Procedures

Surgical Procedure		Dead	Alive	Total	% to All
Airway Reconstruction	N	9	12	21	32.8%
	%	42.9%	57.1%		
Tracheoplasty, cervical	N	4	4	8	12.5%
	%	50.0%	50.0%		
Tracheoplasty, thoracic	N	2	4	6	9.4%
	%	33.3%	66.7%		
Bronchoplasty	N	3	2	5	7.8%
	%	60.0%	40.0%		
Carinal reconstruction	N	0	2	2	3.1%
	%	0.0%	100.0%		
Tracheal Excision	N	4	26	30	46.9%
	%	13.3%	86.7%		
Excision tracheal stenosis, cervical	N	4	16	20	31.3%
	%	20.0%	80.0%		
Excision tracheal stenosis, thoracic	N	0	1	1	1.6%
	%	0.0%	100.0%		
Excision of tracheal tumor, cervical	N	0	4	4	6.3%
	%	0.0%	100.0%		
Excision of tracheal tumor, thoracic	N	0	5	5	7.8%
	%	0.0%	100.0%		
Airway Injury Repair	N	7	6	13	20.3%
	%	53.8%	46.2%		
Suture of tracheal injury, cervical	N	2	3	5	7.8%
	%	40.0%	60.0%		
Suture of tracheal injury, thoracic	N	5	3	8	12.6%
	%	62.5%	37.5%		
Total	N	20	44	64	
	%	31.3%	68.8%		

Table 2. Frequency and Survival Rate with Complications

	Complication Rate		Dead (N=96)		Alive (N=173)		Survival	p value
	N	%	N	%	N	%		
Hemorrhagic								
Gastrointestinal hemorrhage	7	2.6%	4	4.2%	3	1.7%	42.9%	0.252
Mediastinal cannula site bleeding	1	0.4%	1	1.0%	0	0.0%	0.0%	0.357
Peripheral cannula site bleeding	5	1.8%	2	2.1%	3	1.7%	60.0%	1.000
Surgical site bleeding	35	13.0%	20	20.8%	15	8.7%	42.9%	0.007
Pulmonary								
Pulmonary hemorrhage	24	8.9%	12	12.5%	12	6.9%	50.0%	0.179
Pneumothorax	25	9.3%	14	14.6%	11	6.4%	44.0%	0.030

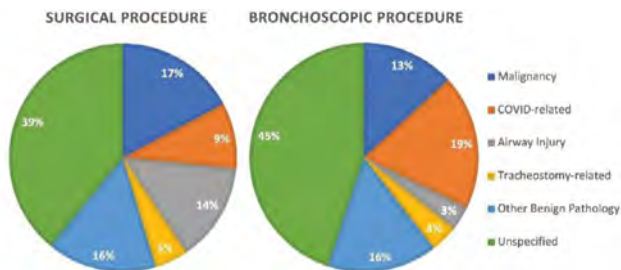


Figure 1. Distribution of the Primary Diagnosis

PULM2

Safe Utilization of a Nitric Oxide-Eluting ECLS System During 72 hours of Veno-Venous ECCO₂R

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Background: Nitric oxide (NO)-eluting biomaterials have been investigated for extracorporeal life support (ECLS) applications due to platelet-inhibitory and anti-inflammatory properties of NO. The short half-life of NO could enable localized thrombus inhibition on device surfaces, mitigating requirement for systemic anticoagulants that cause bleeding. We constructed and evaluated a novel NO-eluting ECLS system (NO-ECLS) with an NO-releasing surface coating and application of NO gas (80 ppm) to membrane oxygenator sweep gas designed for ECLS without heparin. The study objective was to evaluate NO-ECLS in a veno-venous configuration for extracorporeal CO₂ removal (VV-ECCO₂R) in a 72-hour swine ICU model to assess device safety. We hypothesized that NO-ECLS does not elevate systemic methemoglobin and NO metabolite levels relative to conventional ECLS with heparin.

Methods: Uninjured, anesthetized, mechanically ventilated Yorkshire swine (54±2 kg) were cannulated for VV-ECCO₂R (23 Fr Avalon Elite Dual-Lumen Catheter; Gothenburg, Sweden) using the Novalung ECLS System with XLUNG™ Patient Kit (Fresenius Medical Care; Bad Homburg, Germany). Controls (CTRL, n=5) received un-modified ECLS circuits and heparin administration to activated clotting time of 150% baseline. Treatment (NO-ECLS, n=5) received heparin-free ECLS with modified circuits where standard tubing was replaced with NO-eluting tubing swelled with silicone oil and NO donor *S*-nitroso-*N*-acetylpenicillamine. Additionally, NO gas (80ppm) was blended into the oxygenator sweep gas. ECLS was initiated at 1.5 L/min blood flow and 3 L/min sweep gas flow. Blood was collected at baseline (BL), post-initiation of ECLS (PE) and at 6-, 24-, 48- and 72-hours post-ECLS initiation to assess methemoglobin via co-oximetry and NO metabolites nitrate and nitrite via Griess reaction kit (KGE001, R&D Systems; Minneapolis, MN, USA). Time-dependent changes were assessed by one-way mixed model with Dunnett correction. Groups were compared by repeated measures mixed model with Tukey's adjustment (all tests two-sided, alpha=0.05).

Results: Methemoglobin fraction (Fig 1A) and NO metabolite concentrations (Fig 1B) were not different between groups at any time. In NO-ECLS, NO metabolites did not change relative to BL over the study course. In the CTRL group, NO metabolite concentration was significantly reduced relative to BL at 24-72 hours (72-hours = 56 ± 12% decrease, p=0.008).

Conclusion: The NO-ECLS system did not cause systemic alterations in NO metabolites or methemoglobin fraction, demonstrating safety of this approach. Further research investigating the efficacy of NO as a local-acting anticoagulant within the NO-ECLS system is being evaluated in the presence of injury in our lab.

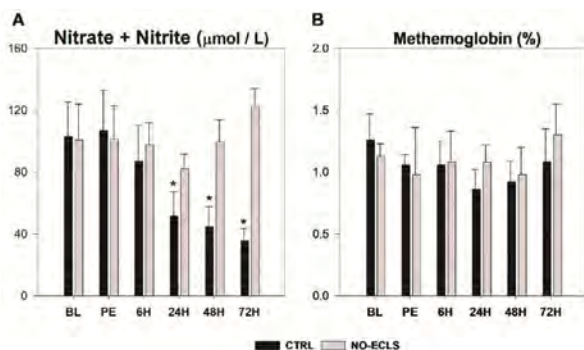


Figure 1. Mean ± std err. plasma nitric oxide (NO) metabolites (A) and methemoglobin fraction (B) in swine that encountered conventional ECLS (CTRL, n=5) versus NO-eluting ECLS + NO gas (NO-ECLS, n=5). *Significant change from BL within group (p<0.05).

PULM3

Combined Respiratory and Renal Support in a Novel Device - Influence of Utilizing Dialysis Fibers Outside-In on Full Blood Clearance and Filtration Efficiency

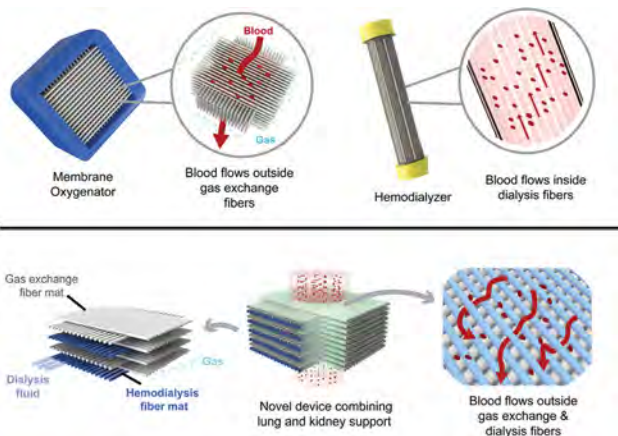
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Background: Up to 70% of extracorporeal membrane oxygenation patients suffer from acute kidney injury. For these patients, our group is developing a novel membrane oxygenator with integrated kidney support. In this device, blood flows outside gas exchange fiber mats and dialysis fiber mats for simultaneous lung support and continuous renal replacement therapy (CRRT). In our previous study, we indicated that 25% of the gas exchange fibers in our oxygenator could be replaced by dialysis fibers maintaining sufficient lung support. However, the effect of outside-in blood flow in the efficiency of dialysis fibers to deliver CRRT is still unknown. Thus, this study aims to evaluate the efficiency of commercial dialyzer membranes utilized outside-in (blood flow outside the fibers) compared to traditional inside-out mode regarding clearance, and ultrafiltration coefficient.

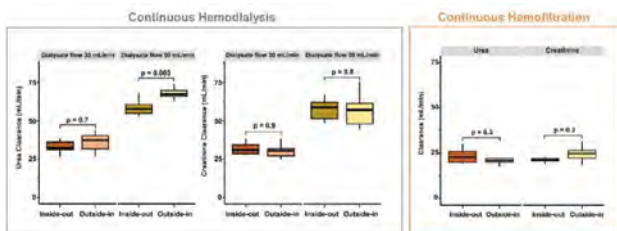
Methods: Commercial dialyzers (1.2 m², asymmetric membranes) were compared during in-vitro blood tests with porcine blood adapting the ISO 8637:2016 during experiments under CRRT conditions. Dialyzers utilized outside-in and in conventional inside-out mode were compared in terms of clearance of urea and creatinine during continuous hemodialysis with a blood flow rate of 150 mL/min, and a dialysate flow rate of 30 mL/min and 50 mL/min. In addition, clearance during continuous hemofiltration with an ultrafiltration rate of 20 mL/min was measured. Fluid removal capacity was evaluated in terms of the dialyzer's ultrafiltration coefficient.

Results: Dialyzers utilized outside-in provided similar levels of urea and creatinine as dialyzers utilized in a traditional inside-out mode during continuous hemodialysis and hemofiltration (p > 0.2), except for experiments with a dialysate flow of 50 mL/min where outside-in dialyzers provided higher urea clearance (p = 0.003). Dialyzers utilized outside-in had an ultrafiltration coefficient of 11.7 mL/h/mmHg, about 4 times lower than the ultrafiltration coefficient achieved in traditional dialyzers. Nevertheless, required fluid removal rates could be achieved if higher transmembrane pressures were applied in the outside-in system. With clinical application in mind, our results indicate that dialyzers utilized outside-in could achieve small solute clearance and fluid removal doses of 20 – 25 mL/kg_{patient}/h comparable to the doses required for kidney support during CRRT, assuming the treatment of a hypothetical 80 kg patient.

Conclusions: Dialyzers utilized outside-in achieved similar urea and creatinine clearance as traditional dialyzers in the continuous hemodialysis and hemofiltration of whole blood. Moreover, comparable fluid removal rates could be achieved by the outside-in fibers if pressures are controlled in the system. We consider this a step towards the development of novel artificial lung with integrated kidney support.



In a novel device combining lung and kidney support, blood would be required to flow and mix outside of both gas exchange and hemodialysis fibers



Clearance by outside-in dialyzers was not statistically significantly different than for traditional inside-out dialyzers ($p > 0.2$), except for urea clearance in experiments with a dialysate flow rate of 50 mL/min ($p = 0.003$).

PULM4

The First Clinical Scale Microfluidic Oxygenator Shows Efficacy in a 48-Hour Combat Injury Model

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Background: Bioinspired microfluidic oxygenators have not previously been scaled to clinically relevant blood flow rates nor tested in translational studies involving injury. Here we report on the first clinical-scale bioinspired microfluidic oxygenator, BLOx2-R1, a 3D branching architecture that precisely controls shear to minimize blood damage, coagulation and inflammation. Testing was done in triplicate in a 48-h round-the-clock swine study using an established model of ARDS due to bilateral chest trauma, against a control hollow fiber membrane oxygenator (HFMO.) The objective was to evaluate whether a physiologically inspired microfluidic design confers better blood health and outcomes after combat injury than an HFMO. We hypothesized that the BLOx2-R1 enables 48 h of lung support after combat relevant trauma without the rise in hydraulic resistance commonly associated with thrombus formation in the HFMO.

Methods: A microfluidic 3D branching design to control blood shear to 3.5 Pa was incorporated in 3 BLOx2-R1 devices scaled to 1.5 L/min blood flow. After general anesthesia, animal preparation and baseline stabilization, mechanically ventilated Yorkshire swine (58 ± 2 kg) underwent bilateral chest trauma, chest tube placement, shock and resuscitation. After injury, 3 BLOx2-R1 devices and 3 HFMO were connected to a percutaneously-placed 23 F veno-venous dual lumen catheter with blood flow driven by a Xenios/Fresenius (Waltham, MA) extracorporeal circuit. All animals were continuously heparinized to 50% above baseline ACT. Hydraulic resistance vs. time was calculated as the ratio of pressure drop to flow rate and normalized by the mean resistance in the 6 - 24 h period.

Results: After injury, all animals demonstrated reduced ratios of partial pressure of oxygen, PaO_2 , to fraction of inspired oxygen, FiO_2 (PFR) (Fig. 1). When compared to control HFMO animals, 2 of the 3 BLOx2-R1 animals showed more successful and sustained recovery in PFR till 48 h after injury without functional derangement. BLOx2-R1 devices maintained stable blood pressure drop, indicative of an absence of occlusive thrombus accumulation, while the one HFMO that completed 48 h duration showed a rapid rise in relative resistance (Fig. 2.)

Conclusion: The BLOx2-R1 microfluidic oxygenator holds promise as a safer and more efficacious treatment for lung injury, pending further large animal testing and eventually clinical trials powered to assess therapeutic benefit.

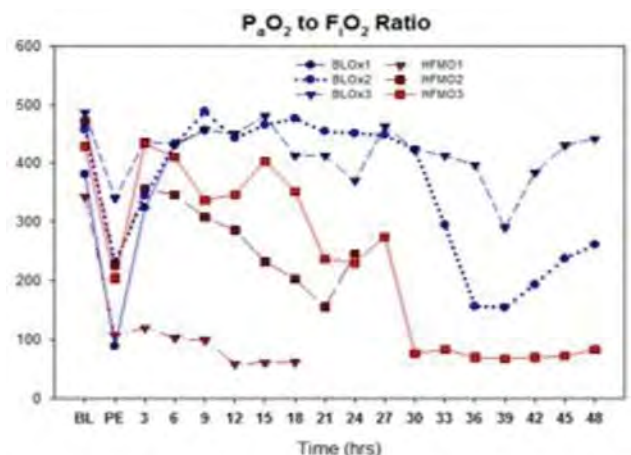


Figure 1. Ratio of PaO_2 to FiO_2 in porcine models at baseline (BL), lung injury (PE) and across 48 h, with BLOx2-R1 microfluidic devices in blue and HFMO controls in red.

Normalized Hydraulic Resistance

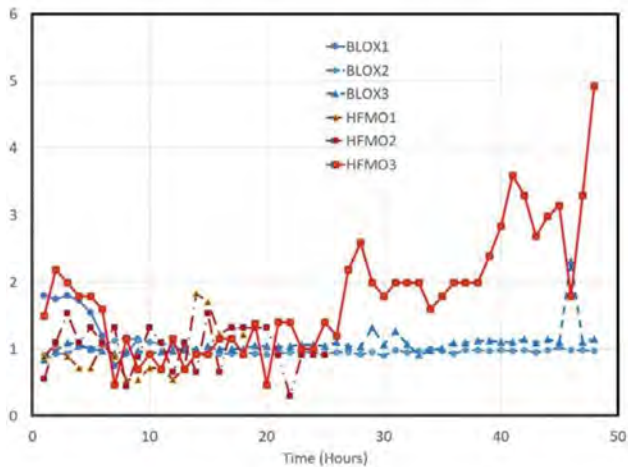


Figure 2. Normalized resistance for BLOx2-R1 (blue) vs. HFMO-treated pigs (red) showing rapid rise for the one HFMO animal that completed the 48-h study.

PULM5

Pop Goes The Weasel If The Weasel Doesn't Pop! A Single-Center Experience With Novel Lung Temperature- And Pressure-Regulated Preservation Devices

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Purpose: Hypothermic pressure-directed lung preservation during *ex vivo* lung transportation could improve post-transplantation outcomes. The most utilized method, ice storage, assures neither optimal pressure control nor uniform temperature preservation. We present an initial case series of two novel FDA-cleared devices designed to maintain hypothermic (4-8 degrees C) temperature regulation during transportation with or without controlled airway pressure (12-15 cm H₂O). These devices align with the clinically recommended inflation pressure range and temperature, thereby addressing conventional risks associated with transport.

Methods: We retrospectively examined the outcomes of 10 patients who underwent bilateral lung transplantation over a 4-month period at our institution. Five patients received donor lungs transported using a temperature-controlled only device (TO), while five patients received donor lungs preserved in a temperature- and pressure-controlled device (TAP). Primary graft dysfunction (PGD) at 24, 48, and 72 hours was the primary outcome. Secondary outcomes included post-reperfusion PaO₂/FiO₂ ratios, intubation time, hospital length of stay (LOS), and ICU LOS.

Results: TAP recipients were insignificantly younger than TO recipients (TAP group 44.6 ± 16.6 vs TO 59.6 ± 13.3 years, p=0.153). Donor characteristics were similar between the two groups. There were no differences in right lung total ischemia time: TO 488 min, [298,509] vs TAP 420 min, [382.5,537], p=0.917 (median, interquartile range [IQR]) and left lung total ischemia time: TO 361 min, [273,534.5] vs TAP 465 min, [299,484.5], p=0.754. ICU length of stay is shorter in the TAP group. (Mean TO 10.8 vs TAP 4.6 days, p=0.05. Time on mechanical ventilation is shorter for the TAP group: TO 52 hrs, [45,110] vs TAP 32 hrs, [25,42], p=0.016. The TAP group had a shorter hospital length of stay: TO 26.5, [12,43] vs TAP 11.5 days, [9,31.5], p=0.149. The TAP group had an insignificantly better intraoperative post-reperfusion PaO₂/FiO₂, TAP: 323.6 ± 23.5, vs TO: 285.2 ± 86.2 (p=0.753), and PGD at 24, 48, and 72 hours were similar between the two groups (all p>0.3).

Conclusion: The innovative preservation system regulates intrabronchial pressure and temperature of donor lung allografts throughout transportation and until implantation. Preliminary observations from our center indicate that this novel device may potentially reduce post-operative ventilation time and ICU length of stay. Conducting analyses on larger cohorts may identify additional benefits of regulating intrabronchial pressure during allograft storage.

Table 1. TAP primary and secondary outcomes

Case	ICU length of stay	Total ventilation hours	Total length of hospital stay in days	Intraoperative P/F	PGD grading at 24/48/72 hours
1	4	45.283	38	347	1/1/1
2	5	31.933	12	343	1/2/1
3	4	25.867	8	320	2/1/1
4	6	38.05	10	288	1/3/1
5	3	24.083	.	320	2/1/1
Median	Mean: 4.6	31.933	11.5	320	1/1/1

Table 2. TO primary and secondary outcomes

Case	ICU length of stay	Total ventilation hours	Total length of hospital stay in days	Intraoperative P/F	PGD grading at 24/48/72 hours
1	7	53.433	11	305	1/1/1
2	17	51.983	39	200	1/2/1
3	6	49.083	14	358	2/1/1
4	6	40.533	.	373	1/3/1
5	18	165.917	44	190	2/1/1
Median	Mean: 10.8	51.983	26.5	305	1/1/1

PULM6

Routine Subclavian Cannulation in Venovenous ECMO is Safe and Efficacious: A Retrospective Study

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Background: In critically ill patients with severe acute respiratory failure supported on Venovenous (V-V) Extracorporeal Membrane Oxygenation (ECMO), the need for multiple large-bore venous catheters may pose peripheral access challenges. Subclavian vein cannulation emerges as a routine alternative when other sites are unsuitable or unavailable. This study assesses outcomes and complication rates, hypothesizing that subclavian access is a safe alternative in V-V ECMO.

Methods: This IRB approved, single-center, retrospective study examines peripheral V-V-ECMO cannulation at an ECMO referral Center from 2020 to 2023. The cohort was stratified by subclavian vein cannulation. Each cannulation site was considered as a separate cannulation event for independent comparison. Comprehensive data was collected through retrospective chart reviews. Descriptive statistics were generated using R statistical computing and analyzed for parametric, non-parametric, and categorical data. Primary endpoints assessed cannulation-specific complications and ECMO-related adverse events. Secondary endpoints were survival to decannulation and survival to discharge.

Result: This study examined 157 V-V ECMO patients over a 3-year period. The cohort was 57% male (N=90), a median age of 44 years old (interquartile range 34-56 years), and a median BMI of 34 kg/m² (interquartile range 28-44). Fifty-five patients (35%) had a subclavian cannula during their ECMO course. The subclavian group had a higher rate of COVID-19 (69%, N=38 vs. 49%, N=49) p=0.016). Both groups had similar comorbidity profiles and pre-ECMO blood gas data. (Table 1) There were 392 unique cannulation events. (Table 2) Clinical variables showed no significant differences in initial pump speed (p=0.3) or flow (p=0.4). When reconfiguring to a single-site cannula, the subclavian vein was used 68% of the time (p < 0.001). Patients with subclavian cannulations had an increased incidence of tracheostomy (82% vs. 60%, p < 0.001). There were no differences in venous thrombosis (p=0.075) or decannulation-related complication rates (p=0.9). There was no survival difference (p = 0.8). Mixed-effect logistic regression showed no site-related differences in adverse events or complication rates. (Figure 1) However, descriptive statistics showed an increased pneumothorax rate in the subclavian arm (p=0.0003). They were all managed by bedside, small-bore chest tube placement.

Conclusion: Subclavian cannulation can be a safe, efficacious and non-inferior strategy in patients supported with V-V ECMO. It occurred more frequently in older patients and those with COVID-19. The rates of survival to decannulation or discharge were similar between the two groups. There were no differences in the odds of composite complications or adverse-event rates by cannulation site when adjusting for confounders in the mixed-effects model. These data add to the growing literature in support of ECMO therapy and motivate for newer clinical trials.

Table 1. Comparison of Demographic, Clinical Characteristics, and ECMO Course Between Subclavian and Non-Subclavian Cohorts

	Overall N = 127 ¹		Non-subclavian N = 102 ¹		Subclavian N = 25 ¹		p-value ²
Age at Cannulation	44	34-55	42	31-53	49	37-58	0.018
Sex							
Female	67	43%	41	40%	26	47%	0.4
Male	60	57%	61	60%	29	53%	
BMI	34	28-44	33	29-44	34	28-44	>0.9
Co-morbidities							
Asthma	41	29%	28	28%	13	23%	0.4
Hypertension	84	54%	59	58%	25	45%	0.14
Heart failure	18	11%	14	14%	4	7.3%	0.3
Coronary artery disease	12	7.6%	8	7.8%	4	7.3%	>0.9
Malignancy	3	1.9%	2	2.0%	1	3.8%	>0.9
Liver disease	6	3.8%	6	5.9%	0	0%	0.092
Substance abuse	7	4.5%	7	6.9%	0	0%	0.10
Perinatal	10	6.4%	8	5.9%	2	7.3%	0.7
VW	2	1.3%	2	2.0%	0	0%	0.5
None of the above	41	29%	20	20%	21	84%	0.013
Etiology of illness for VV ECMO							
Viral (e.g. Influenza, encephalitis, etc.)	91	59%	52	51%	41	73%	
Bacterial (e.g. MRSA, pseudomonas, etc.)	7	4.5%	6	5.9%	1	3.8%	0.2
Aspiration	8	2.5%	3	2.9%	1	3.8%	
Respiratory failure, not ARDS	16	10%	12	12%	4	7.3%	
Post-operative ARDS	7	4.5%	5	4.9%	2	3.8%	
Non post-operative ARDS	8	4.9%	3	2.9%	0	0%	
Other	27	37%	21	21%	6	11%	
Pre-cannulation							
Positive COVID-19 test	87	56%	49	48%	38	69%	0.016
COVID in AR	79	50%	57	57%	22	40%	0.058
Renal Replacement Therapy	24	15%	16	16%	8	15%	0.8
Lactate	2.10	1.31-3.75	2.28	1.41-3.98	1.73	1.18-2.67	0.058
pH	7.27	7.19-7.37	7.26	7.19-7.37	7.29	7.18-7.41	0.13
pO2	56	43-71	55	45-74	58	41-73	<0.9
pO2	78	58-90	70	57-90	73	61-90	0.5
HCO3	26	22-30	25	21-29	27	22-32	0.8
SO2 (in from ABG)	91	85-95	90	85-94	92	86-98	0.2
FiO2 (in)	100	80-100	100	80-100	100	90-100	0.7
Treatment through Admission	95	57%	47	46%	42	72%	<0.001
Decannulated from ECMO	115	73%	75	74%	40	72%	>0.9
Discharge status							
Alive	112	71%	72	71%	40	73%	0.8
Dead	49	29%	30	29%	15	27%	
Discharge location							
Home	53	47%	41	57%	12	30%	0.002
Rehab or LTAC	44	39%	25	35%	19	44%	
Transfer to CCU	15	13%	6	8.3%	9	21%	

¹Medians and IQRs or N and percentiles presented

²p-Values were calculated by Mann-Whitney U, Fisher Exact, or Chi-Square Tests, as appropriate

ARI = acute kidney injury

ARDS = acute respiratory distress syndrome

COVID = chronic kidney disease

LTAC = long-term acute care

CCU = cardiac care unit

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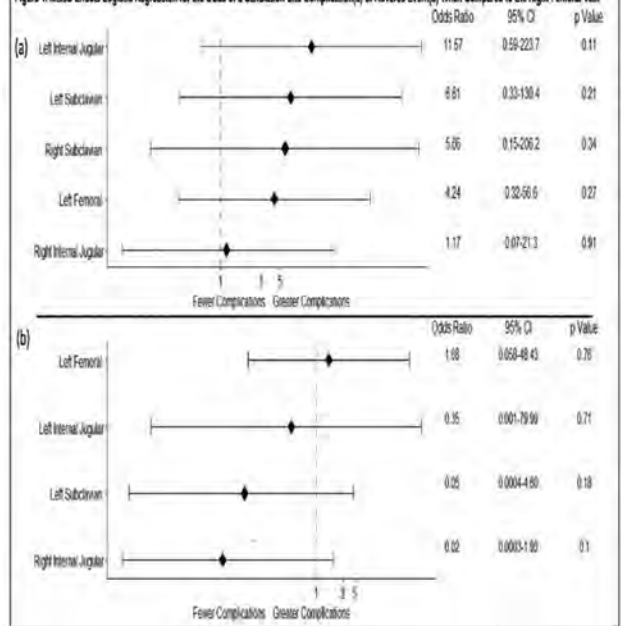
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Figure 1. Mixed-Effects Logistic Regression for the Odds of a Cannulation Site Complication(s) or Adverse Event(s) When Compared to the Right Femoral Vein



Odds ratios were calculated with a mixed-effects logistic regression model for the odds of complications. The model contained fixed effects to control for cannulation sequence, cannula size, and a random effect term for the patient factors. No adverse events were observed in the right subclavian group, precluding the calculation of odds ratios for that site.

Table 2: Comparison of Cannulation Specific Details Between Subclavian and Non-Subclavian Cannulas

	Non-subclavian N = 821 ¹		Subclavian N = 73 ¹		p-value ²
Location					
Left Femoral	35	11%	0	0%	<0.001
Left Internal Jugular	14	4.4%	0	0%	
Left Subclavian	0	0%	66	93%	
Right Femoral	141	44%	0	0%	
Right Internal Jugular	131	41%	0	0%	
Right Subclavian	0	0%	5	7.0%	
Type of Cannula					
Initial Drainage Cannula	147	46%	0	0%	<0.001
Initial Return Cannula	138	43%	9	13%	
Initial Single Site	6	1.9%	4	5.6%	
Transition to Single Site	7	2.2%	25	35%	
Additional Cannula	7	2.2%	30	42%	
Exchanged Drainage Cannula	9	2.8%	1	1.4%	
Exchanged Return Cannula	7	2.2%	2	2.8%	
Site	25.0	20.0-29.0	23.0	23.0-29.0	0.030
Initial pump speed (RPMs)	3,015	2,830-3,435	3,215	2,903-3,475	0.3
Initial flow (LPM)	4.06	3.68-4.70	4.20	3.89-4.86	0.3
Initial VV-ECMO type					
Dual Site	312	97%	67	94%	0.12
Single Site	5	1.6%	4	5.6%	
RV support	4	1.2%	0	0%	
Dual Cannula Exchange	8	2.5%	2	2.9%	0.7
Adverse events					
Cannula malposition requiring repositioning or exchange	26	8.1%	7	9.9%	0.6
Bleeding requiring intervention	1	0.3%	0	0%	>0.9
Cerebrovascular accident (ICH or ischemic stroke)	12	3.7%	1	1.8%	0.5
Complications					
Unsuccessful cannulation attempt/abandoned site	4	1.2%	3	4.2%	0.12
Ipsilateral pneumothorax	4	1.2%	7	9.6%	0.0003
Ipsilateral hemothorax	0	0%	0	0%	>0.9
Ipsilateral limb congestion	3	0.9%	0	0%	>0.9
Other	4	1.2%	2	2.8%	0.3
Complications with Decannulation					
Bleeding	3	0.9%	0	0%	>0.9
Air embolism	0	0%	0	0%	>0.9
Limb ischemia	0	0%	0	0%	>0.9
Post-decannulation DVT	111	50%	30	64%	0.075

¹Medians and IQRs or N and percentiles presented

²p-Values were calculated by Mann-Whitney U, Fisher Exact, or Chi-Square Tests, as appropriate

PULM7

A Novel Approach for Highly-Efficient IntraVascular Membrane Oxygenation: In Vitro Proof-of-Concept Catheter Prototype Testing Under Mixed Venous Conditions

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Background: There is an urgent need for alternative therapies in ARDS that enable oxygen delivery *independent* of the lungs. Current technologies such as extracorporeal membrane oxygenation (ECMO) are effective, but resource-intensive with serious side effects. Our team has developed a novel approach to intravascular membrane oxygenation that relies on pressurized oxygen flowing through bundles of *non-porous* hollow fiber membranes undergoing multi-phasic angular oscillation. We report here on *in vitro* gas transfer efficiency testing of the first full-surface area prototype catheters.

Methods: Prototype catheters (284 fibers spread across 22 mm diameter, 31.8 cm long, and $9.37 \times 10^{-2} \text{ m}^2$ area) were built using *non-porous* polymer hollow fiber membranes (HFM) potted in end-cap manifolds (Fig 1). Pressurized oxygen was delivered to the HFMs via a central shaft connected to the distal end-cap which also served to couple the HFM bundle to a stepper-motor. The catheter was placed in a circuit containing a mock vena cava (22.2 mm ID) with porcine whole blood flowing at 5 L min^{-1} . The HFM bundle was rotated through various macro (α) angles of oscillation superimposed with micro (β) angles at up to $5200 \text{ deg sec}^{-1}$. An ECMO membrane oxygenator (Quadrox-I, Getinge) was used to de-oxygenate the inlet blood and hold it under stable mixed venous conditions according to ISO 7199. Sampling ports were placed at the inlet and outlet for blood gas analysis. A cardiopulmonary bypass bubble trap (Capiiox, Terumo) was placed immediately downstream from the catheter prototype to assess for any potential oxygen gas emboli.

Results: The prototype catheter delivered 40.7 ± 1.5 and $48.8 \pm 4.6 \text{ mL O}_2 \text{ min}^{-1}$ when tested at an average of 1.3 and 1.8 bar absolute fiber intraluminal oxygen pressure, respectively. The oxygen transfer rates were highly dependent on inlet blood oxygen content. Rates as high as $54.9 \text{ mL O}_2 \text{ min}^{-1}$ were recorded. This corresponds to an oxygen transfer efficiency of up to $586 \text{ mL O}_2 \text{ min}^{-1} \text{ m}^{-2}$. Oxyhemoglobin % saturation increased between 3-6% in a single pass as blood flowed past our device at 5 L min^{-1} . With continuous operation, less than 10 mL of gaseous oxygen per hour was collected in the bubble trap.

Conclusion: This work demonstrates the ability to deliver clinically relevant ($>50 \text{ mL min}^{-1}$) quantities of oxygen within the confines of the intravascular space using our novel membrane oxygenation catheter. To our knowledge, we report the highest oxygen transfer efficiency for any membrane oxygenator published in the literature. This high efficiency allows for a compact catheter-based device much smaller than previous attempts at intravascular oxygenation and motivates ongoing product development. Successful development of this catheter would allow clinicians to provide supplemental intravenous oxygen to patients with ARDS, which might enable the weaning of intensity of other modalities of respiratory support as part of a lung-protective ventilation strategy.

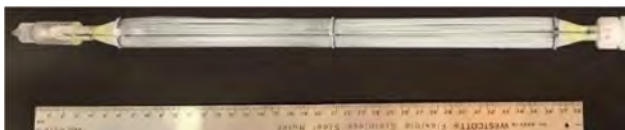


Figure 1. The IntraVascular Membrane Oxygenator Catheter prototype has an oxygen transfer efficiency of up to $586 \text{ mL O}_2 \text{ min}^{-1} \text{ m}^{-2}$ when tested *in vitro* in accordance with ISO 7199.

PULM8

Negative Pressure Ventilation with the Penn State Torso Expander Improves Respiratory Mechanics

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Background: Negative pressure ventilation (NPV) was used to support natural breathing before positive pressure ventilation (PPV) became prevalent. However, conventional NPV devices that require tanks or cuirasses are large and reduce access of care. PPV effectively increases tidal volume (TV) but tends to over-inflate and damage aerated lung instead of opening atelectatic and dependent lung. This is especially relevant to neonates with Respiratory Distress Syndrome (RDS). We have developed a Torso Expander (TE) - a soft, neonatal size, vest-like device made of silicone tubes filled with air that provides negative distending pressure to the torso. By synchronizing the TE inflation/deflation to the patient's respiratory cycle, referred to as Torso Assist Ventilation (TAV), the device works in synergy with the ventilator or the patient's natural breathing to reduce atelectasis and increase respiratory compliance. We are reporting the results of exploratory studies in a piglet animal model (2.5-3.5 kg).

Method: Our early focus was on developing a consistent severe RDS protocol ($\text{PaO}_2/\text{FiO}_2 < 100$ for at least 30 min) achieved by surfactant washout with 30 ml/kg warm saline lavage. TAV was synchronized to invasive pressure control volume ventilation, targeting 5-6 ml/kg tidal volume (TV). In the last two experiments TAV was tested without saline lavage, supported only by continuous positive airway pressure (CPAP) with PEEP of 5 cm water and TAV synchronized to spontaneous breathing. Physiologic parameters were monitored: arterial, esophageal, gastric, abdominal pressures and airway pressure and flow (measured by pneumotach) and diaphragm electrical activity (Edi peak). Tidal volume, peak inspiratory pressure, and dynamic compliance (Cdyn) and Edi peak were compared during baseline, TAV application and post TAV stable period.

Results: In a severe RDS protocol (N=12), oxygenation improved up to 284 %. When TV was less than ventilator targeted TV during baseline, TAV increased the TV by 20-80%. When TV was already at the level set by the ventilator, peak inspiratory pressure was reduced by 3-25%. Cdyn increased 30-95% during TAV and reduced to same or slightly higher than baseline levels post TAV. During invasive CPAP support, the work of breathing decreased with reduction in respiratory rate (18%), and Edi peak (41%), while TV increased (20%). During non-invasive mask CPAP and no ventilatory support (animal only), TV increased 62% and 14% respectively.

Conclusion: The Penn State Torso Expander is a compact and non-invasive device for applying negative distending pressure to the torso. In an animal model of severe neonatal RDS on ventilator support, the device improved oxygenation and increased Cdyn resulting in increased TV and/or reduced peak inspiratory pressure. These changes were also seen in a model of spontaneous breathing with CPAP support.

PULM9

24-hour normothermic ex situ lung perfusion in the portable ECMO based system: Pilot study

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Background: Continuous *ex situ* machine perfusion of the donor lung has been proposed as an alternative and superior method of donor organ preservation compared to cold static storage especially during the transport time. The new portable and universal *ex situ* lungs perfusion system based on ECMO technology opens new horizons in the transplant field, and beyond for isolated organs resuscitation, treatment, diagnostics, modification, and long term transportation (24 h).

Methods: Five donors, weighing 74±13.1kg, included for this study. Until donor lungs harvesting, the study received approval through the responsible ethics committee at our institution. Heparinized whole blood collection (1500±150ml.) was performed prior to multiorgan harvesting. After regular heart harvesting the donor lung were flushed with room temperature Perfadex solution in retrograde and antegrade fashion to eliminate possible blood clots. Organ harvesting, followed by back table pulmonary artery/main branches and trachea cannulation performed, and connected to the portable system for normothermic *ex situ* lung perfusion. Regular ECMO centrifugal pump, oxygenator, and circuit were used to maintain 0.6-0.8 liters per minute flow into the pulmonary artery. Perfusate oxygenation and gas management provided by special room air flow generator (0.1 liters per minute of airflow with addition of 6-7% of CO₂). Lung ventilation with portable ventilator (our institution development) sustained protective respiratory management and assessment.

Continues hemofiltration was applied during whole period of isolated lung perfusion in order to protect and improve donor organ function. The perfusion process was accompanied with laboratory, ventilation assessment, and computed tomography assessment. After the end of perfusion period of 24 hours, donor lung is disconnected from the system and studied morphologically.

Results: Mean±SD ischemic time prior to machine reperfusion was 43.2±3.3 minutes. Mean *ex situ* perfusion and ventilation time was 24.3±3.5 hours. All isolated lungs had normal ventilation parameters, as well as stable perfusion, laboratory, bronchoscopy, CT and histological characteristics.

Conclusions: Normothermic *ex situ* lung perfusion provides near physiologic and reproducible approach to sustain the isolated organ for 24-hours period.

PULM10

Exploring the Impact of Thrombocytopenia on Outcomes in Acute Respiratory Distress Syndrome (ARDS) Patients: A Comprehensive Analysis Using the National Readmission Database (NRD)

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Background: Acute Respiratory Distress Syndrome (ARDS) is a critical medical condition associated with high morbidity and mortality. Thrombocytopenia, characterized by low platelet counts, has been recognized as a potential complicating factor in ARDS. This study aims to explore the impact of thrombocytopenia on the outcomes of ARDS patients using data from the National Readmission Database (NRD) from 2017 to 2020.

Methods: The study encompassed a cohort of 116,662 ARDS patients, categorized into sub-cohorts based on the presence or absence of thrombocytopenia. Various baseline characteristics were analyzed, including demographics, age groups, length of stay (LOS), household income, total charges, and comorbidities. The study also investigated ECMO status in ARDS patients and identified predictors of mortality using logistic regression models.

Results: The results highlighted significant disparities between the thrombocytopenia (33,663) and non-thrombocytopenia (176,972) groups in a cohort of 210,635 patients with ARDS out of 70,490,815 discharges in the years 2017-2020. Thrombocytopenic patients exhibited a higher percentage of certain comorbidities such as congestive heart failure (29% vs. 28%, p<0.01), Moderate to severe liver disease (9.63% vs. 3.07%, p<0.01), longer LOS (84% vs. 77%, p<0.001), and increased total charges of more than 100k (81% vs. 69%, p<0.01). Furthermore, the thrombocytopenia group demonstrated a notably higher mortality rate during hospitalization compared to the non-thrombocytopenia group (56% vs. 44%, p<0.001). The examination of ECMO status in ARDS patients revealed variations in mortality rates among different ECMO types. Thrombocytopenia emerged as an independent predictor of mortality, alongside factors such as age, gender, LOS, primary expected payer/insurance, and various comorbidities.

Conclusion: This study provides valuable insights into the factors influencing the outcomes of ARDS patients, emphasizing the significance of thrombocytopenia as a predictor of mortality. The findings underscore the importance of considering thrombocytopenia in the clinical management of ARDS patients. Recognizing these risk factors may guide our teams in tailoring treatment strategies and improving patient outcomes in the challenging context of ARDS.

SHOCK1

Mechanical circulatory devices for patients with cardiogenic shock: should we go with the new or stick to the old?

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Background: Despite advances in therapeutic options, the management of cardiogenic shock (CS) remains challenging and is still associated with high mortality rates in the intensive care unit (ICU) nowadays. Although short-term mechanical circulatory support (MCS) is an alternative to refractory cases and is frequently used in clinical practice, there is still controversy in the literature about its potential benefits. Moreover, there is conflicting data on what would be the best device for short-term MCS in patients with CS. The objective of this study was to compare the mortality of patients with CS who received, or not, MCS with different devices within 3 days of the CS diagnosis in a large international database.

Methods: This is an observational, retrospective cohort, with data collected from the TriNetX platform (TriNetX, Cambridge, MA, United States), a global research network which provides access to de-identified electronic medical records across large healthcare organizations. Patients ≥ 18 years and a diagnosis of CS were initially selected and patients were considered as receiving mechanical circulatory support (MCS) if an intra-aortic balloon pump (IABP), an Impella device or VA-ECMO was initiated within 3 days from the time of the diagnosis of CS. The 30-Day and 90-Day mortality was analyzed and 30-Day mortality was compared between patients with CS who did not receive any MCS, and patients supported with IABP, Impella and VA ECMO alone or combined. The 30-Day mortality was compared before and after propensity score matching considering 21 variables such as age, sex, race, comorbidities, medications, laboratory exams (hemoglobin levels, platelet count, c-reactive protein, troponin, atrial natriuretic peptide, bilirubin, creatinine, lactate, oxygen saturation) and left ventricular ejection fraction (LVEF). Kaplan-Meier estimated survival curves were also created and analyzed.

Results: A total of 191,735 patients with CS were identified in the TriNetX database, with an overall 32.6% mortality at 30 days. The number of patients with CS, the 30-Day and 90-Day mortality rates with different MCS devices are presented in table 1. The 30-Day mortality comparisons between groups are shown in table 2 with odds ratio, 95% CI and p-values before and after propensity matching. Figures 1 to 3 show the Kaplan-Meier estimated survival curves for the comparison between the 3 devices used for MCS.

Conclusion: Recognizing all inherent limitations related to this study's methodology, our results suggest that in patients with CS, the use of IABP may be associated with a lower 30-day mortality in comparison to patients who did not receive any MCS or patients treated with other MCS devices. More randomized trials are urgently needed to clarify which patients would most benefit from MCS in CS and what devices are associated with better clinical outcomes and less complications.



Figure 1. Kaplan-Meier curves after propensity matching for comparison between CS patients treated with IABP in comparison to Impella and VA ECMO.



Figure 2. Kaplan-Meier curves after propensity matching for comparison between CS patients treated with Impella in comparison to VA ECMO.



Figure 3. Kaplan-Meier curves before and after propensity matching for comparison between CS patients treated with VA-ECMO + IABP in comparison to VA-ECMO + Impella.

Table 1. Number of patients with CS, 30-Day and 90-Day mortality with different MCS devices.

	30-Day mortality n (%)	90-Day mortality n (%)
CS without any MCS n = 169,140	55,560 (32.9)	64,494 (38.1)
CS + IABP alone n = 12,024	3,435 (28.6)	3,949 (32.8)
CS + Impella alone n = 3,705	1,614 (43.6)	1,741 (47.0)
CS + IABP + Impella n = 972	448 (46.1)	487 (50.1)
CS + VA-ECMO n = 3,734	1,804 (48.3)	2,026 (54.3)
CS + VA ECMO + IABP n = 676	339 (50.1)	377 (55.8)
CS + VA ECMO + Impella n = 806	406 (50.4)	451 (56.0)

CS: cardiogenic shock; MCS: mechanical circulatory support; IABP: intra-aortic balloon pump; VA-ECMO: veno-arterial extracorporeal membrane oxygenation

Table 2. 30-Day mortality comparisons between groups of patients with CS and different MCS devices before and after propensity matching.

	Before propensity matching 30-day mortality %; OR (95% CI), p-value	After propensity matching 30-day mortality %; OR (95% CI), p-value
CS + IABP vs CS without MCS	28.6 vs 32.9; 0.82 (0.78 - 0.85), p<0.001	28.6 vs 32.6; 0.83 (0.78 - 0.87), p<0.001
CS + Impella vs CS without MCS	43.6 vs 32.9; 1.58 (1.48 - 1.68), p<0.001	43.6 vs 35.5; 1.40 (1.28 - 1.54), p<0.001
CS + VA-ECMO vs CS without MCS	48.3 vs 32.9; 1.90 (1.78 - 2.03), p<0.001	48.3 vs 31.4; 2.05 (1.86 - 2.25), p<0.001
CS + IABP vs CS + Impella	28.6 vs 43.6; 0.52 (0.48 - 0.56), p<0.001	30.2 vs 43.6; 0.56 (0.51 - 0.62), p<0.001
CS + IABP vs CS + VA-ECMO	28.6 vs 48.3; 0.43 (0.40 - 0.46), p<0.001	26.2 vs 49.3; 0.37 (0.33 - 0.40), p<0.001
CS + IABP vs CS + VA-ECMO + IABP	28.6 vs 50.1; 0.40 (0.34 - 0.47), p<0.001	29.0 vs 50.6; 0.40 (0.32 - 0.50), p<0.001
CS + IABP vs CS + VA-ECMO + Impella	28.6 vs 50.4; 0.39 (0.34 - 0.46), p<0.001	25.5 vs 50.6; 0.33 (0.27 - 0.41), p<0.001

CS: cardiogenic shock; MCS: mechanical circulatory support; OR: odds ratio; CI: confidence interval; IABP: intra-aortic balloon pump; VA-ECMO: veno-arterial extracorporeal membrane oxygenation

SHOCK2

Impella 5.5 And CP Flow Is Overestimated By The Smartassist Console Under Pulsatile And Non-Pulsatile Conditions

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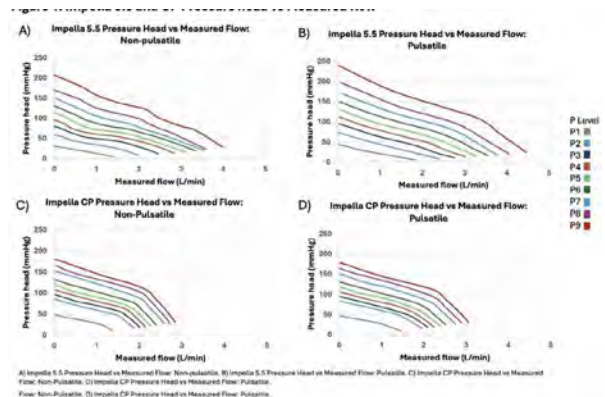
Background: The Impella 5.5 and CP devices are routinely used in the management of critically ill patients with cardiogenic shock. The pressure head-flow (HQ) relationship of these devices has not yet been described. We sought to establish the HQ relationship at varying P-levels and haematocrits (Hct) and compare the measured flow to that obtained from the SmartAssist console.

Methods: We created a pneumatically powered silicone, biventricular mock circulatory loop (MCL) which incorporated pulmonary and systemic vascular resistance and compliance. An Impella 5.5 device was inserted across a bioprosthetic aortic valve into the left ventricle (LV). To prevent flow around the device inlet and outlet cannula a second bioprosthetic valve was placed in reverse orientation. Two Millar Mikro-Tip pressure catheters measured instantaneous pressure difference between the LV and aorta with the difference representing the pump pressure head. A calibrated clamp-on flow meter measured instantaneous pump flow through the aorta. A 40% glycerol solution was circulated in the MCL and heated via an in-line water bath to three different temperatures to simulate different Hct (29, 33 and 37 degrees Celsius, corresponding to Hct 41%, 37% and 33%). Measurements were taken at each P level (P1-P9) at steady, non-pulsatile state at each temperature (29, 33 and 37 degrees Celsius). The experimental protocol was then repeated in a pulsatile state. The Impella 5.5 was then replaced with an Impella CP and the entire experimental protocol was repeated. Statistical analysis was performed using paired t-test or one-way analysis of variance, as appropriate.

Results: The SmartAssist console overestimated device flow when compared to measured flow for the Impella 5.5 (2.48 ± 2.0 vs 1.80 ± 1.27 L/min), (mean difference 0.69 L/min, SD: 1.09 L/min, 95% CI: 0.79 - 0.59 L/min, p<0.0001) and the Impella CP (2.1 ± 1.20 vs 1.39 ± 0.95 L/min) (mean difference 0.72 L/min, SD: 0.3 L/min, 95% CI: 0.75 - 0.69 L/min, p<0.0001). Console estimated peak flow for each device was higher than the measured peak flow (6.2 vs 5.52 L/min for Impella 5.5; 4.2 vs 3.13 L/min for Impella CP).

The HQ relationship was established for both the Impella 5.5 and CP devices at both a steady state and a pulsatile state (Figure 1). The HQ relationship was unchanged for each device during each state for different Hct. Hysteresis loops were created for the Impella 5.5 and CP during pulsatile function and were largely unchanged between the different P levels and at different Hct.

Conclusion: There is a significant discordance between console reported and measured pump flow the Impella 5.5 and CP devices at all P-levels and across different Hct. This may have significant implications for the efficacy and use of these devices in clinical practice.



SHOCK3

Introduction of Guideline Directed Medical Therapy and Native Heart Recovery in Patients Supported by Impella 5.5

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Background: Cardiogenic shock is associated with high morbidity and mortality. The use of mechanical support has been demonstrated to improve outcomes in select groups of patients. While end-organ recovery and survival is the main goal of early MCS, many patients are left with LV dysfunction requiring advanced therapies. Early LV unloading with the Impella 5.5 device (Abiomed, Danvers, MA) however, has been associated with improved native heart recovery in a variety of etiologies of cardiogenic shock. As a large nontransplant cardiac program with extensive impella 5.5 experience, we seek to determine predictors of native heart recovery and propose an algorithm for GDMT introduction and titration in this patient population.

Methods: A retrospective review was conducted of all impella 5.5 supported patients cared for at our center between October 2019-April 2023.

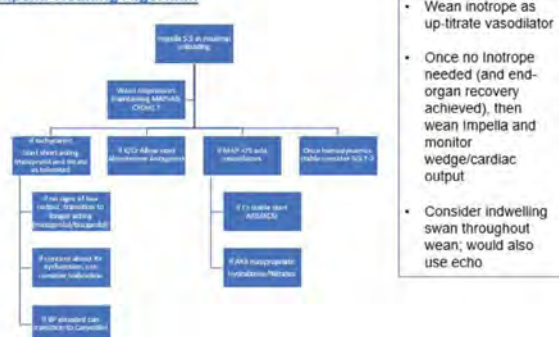
Results: 150 patients were supported by Impella 5.5 at our center. 115 were male and mean age was 63.4 years. AMI accounted for 80 patients, 49 patients were supported for acute decompensated heart failure and the remaining patients were supported for postcardiotomy shock or periprocedural support. In the AMI group, 60 patients were revascularized with primary PCI while 15 patients received CABG. All patients were recovered on impella 5.5 following revascularization. In the ADHF group, 34 patients were supported as bridge to advanced therapies and the remaining as bridge to decision.

Following adequate time on support, 74 patients had native heart recovery with EF range 20-55% and 65 of these patients were discharged on GDMT alone, while 9 patients required continuous inotropes. GDMT was introduced based on the below algorithm.

The 65 patient recovered to GDMT 31 had presented with AMI and most received some form of revascularization, with 30 post PCI, 21 post CABG. Ten of the patient's received planned impella 5.5 for procedural support, and 2 patients had postcardiotomy shock. At time of discharge from the acute hospitalization, 29 patients on at least 3 pillars of GDMT, 20 patients on at least 2 pillars and 15 patients on only 1 pillar at time of discharge. Of this group of recovered patients 2 patients moved on to needing advanced therapies within 1 year (1 LVAD, 1 transplant)

Conclusion: Left ventricular unloading with the Impella 5.5 device is associated with native heart recovery in a select group of patients, particularly those revascularized with impella support for ischemic disease regardless of initial presentation. Minimizing vasoactive drugs and enabling myocardial rest, while introducing early neurohormonal blockade in this patient population is key for native heart recovery. Early identification of these potential patients and aggressive GDMT titration can result in improved sustainability of native heart recovery and avoid or delay the need for advanced therapies.

GDMT/Impella Weaning Algorithm



SHOCK4

Health-Related Quality Of Life Measures In Patients With Acute Decompensated Heart Failure Before And After Axillary Mechanical Circulatory Support

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Background: The Kansas City Cardiomyopathy Questionnaire (KCCQ)-12 is a standardized self-reporting tool used to assess the health status of patients with Heart failure. Patients with end-stage heart failure in cardiogenic shock (HFCS) requiring axillary mechanical circulatory support (aMCS) may change their quality of life (QOL). However, data regarding the impact of aMCS and inpatient hospitalization has not been reported in the HFCS population to date. We assessed the differences between admission and two weeks post-Impella 5.5 placement KCCQ-12 scores in patients with HFCS.

Methods: We performed a prospective cohort analysis on patients with Impella 5.5 supported for HFCS awaiting organ transplantation or recovery at Mayo Clinic in Florida between May 2023 and July 2023. Inpatients completed the KCCQ-12 at admission and after Impella 5.5 placement. By using a Wilcoxon rank test, we evaluated the changes in KCCQ-12 scores with a p value of <.05 as significant.

Results: 15 patients were enrolled in our study. All patients were NYHA 3b or 4 and supported with single or dual inotrope with decompensation and progression to HFCS requiring aMCS placement. On admission, most patients reported they were overall feeling poor to fair (46.7%) and just 20% of them were feeling fair to good according to the summary KCCQ-12 score. However, after the Impella 5.5 placement, the percentage of patients that were feeling poor to fair dropped to 33.3% with an increase in the number of patients feeling fair to good (40%). The median KCCQ-12 overall summary score after the placement of Impella 5.5 was significantly higher than before the device (50.52 vs. 28.13, p=.005). When analyzing the KCCQ-12 domains, the median scores in the symptom frequency domain (70.83 vs. 43.75, p=.009), and the quality-of-life domain (50 vs. 12.5, p:0.023) significantly improved after device placement.

Conclusion: Our data highlights the potential for patients with HFCS to have a significant improvement in their overall health status, symptom frequency, and quality of life within just two weeks of receiving an Impella 5.5 device. This has important implications for making clinical decisions and optimizing treatment approaches for this group of critically ill patient population.

Table 1 Demographic, Clinical and Surgical Characteristics				Table 2 Clinical Outcomes			
	Group A (n=25) [mean (SD) ± s.d.]	Group B (n=26) [mean (SD) ± s.d.]	P value (Mann-Whitney U test)		Group A (n=25) [mean (SD) ± s.d.]	Group B (n=26) [mean (SD) ± s.d.]	P value (Mann-Whitney U test)
Age (years)	58.7 ± 5.7	63.8 ± 6.1	0.3028	LOS in hospital (days)	33.1 ± 25.7	38.5 ± 22.9	0.5533
Sex (male)	15 (60)	19 (73)	0.0824	LOS in intensive care (days)	11.5 ± 10.5	12.2 ± 11.5	0.2244
Length of stay (days)	15 (5.0)	17 (6.5)	0.0824	LOS in hospital (days)	22.5 ± 9.8	17.0 ± 8.8	0.0011
All deaths				Complications	3 (12)	1 (4)	0.3439
A	0 (0)	0 (0)	1.0	Neurological sequelae (stroke)	0 (0)	1 (4)	0.4944
B	0 (0)	0 (0)	0.0005	Subdural haematomas	0 (0)	0 (0)	1.0
C	1 (4)	1 (4)	1.0	Brain abscess	0 (0)	0 (0)	1.0
D	0 (0)	0 (0)	0.0005	Ischemic stroke	0 (0)	0 (0)	1.0
E	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
F	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
G	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
H	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
I	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
J	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
K	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
L	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
M	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
N	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
O	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
P	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
Q	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
R	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
S	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
T	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
U	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
V	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
W	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
X	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
Y	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
Z	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AA	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AB	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AC	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AD	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AE	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AF	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AG	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AH	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AI	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AJ	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AK	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AL	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AM	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AN	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AO	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AP	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AQ	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AR	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AS	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AT	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AU	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AV	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AW	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0
AX	0 (0)	0 (0)	0.0005	Brain abscess	0 (0)	0 (0)	1.0

SHOCK7

Clinical Characteristics and Outcomes of Temporary Mechanical Circulatory Support at a Novel Veterans Affairs Heart Failure Program

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Background: Use of Mechanical Circulatory Support (MCS) continues to expand as its role evolves in the treatment of acute cardiogenic shock and respiratory failure. Among high-risk populations, a thorough understanding of its effects is paramount to maximize optimal outcomes and mitigate risk. The Michael E. DeBakey Veterans Affairs Medical Center (MDVAMC) has launched an all-inclusive heart failure program including ventricular assist devices (VAD), orthotopic heart transplant, and short-term MCS. We describe the clinical characteristics of Veterans who received temporary MCS and report outcomes.

Methods: All patients who received extracorporeal life support (ECLS) including veno-arterial (VA) or veno-venous (VV) extracorporeal membrane oxygenation (ECMO), extracorporeal cardiopulmonary resuscitation (eCPR), or Impella 5.5 from October 14th, 2020 to December 31st, 2023 at MDVAMC were retrospectively reviewed. Baseline patient characteristics, co-morbid illness, MCS indication, available laboratory values, and patient outcomes were analyzed. Student's t-test and Fisher's exact test were used to compare means and categorical values, respectively.

Results: A total of 32 patients received ECLS (ECMO- VA, 40% or VV, 13%, eCPR, 16%, and Impella, 31%). Mean age at deployment was 62.3 (SD 10.75). Most common indications included cardiogenic shock (44%), cardiac arrest (19%), and respiratory failure (13%). 69% survived initial ECLS deployment. Of those, 41% survived to discharge. Preoperative characteristics showed higher (mean, SD) BMI (31, 5.93), baseline creatinine (1.82, 1.38), and lower ejection fraction, EF (36.73%, 15.99) than the general population. Of the cardiovascular risk factors, 87.5% had hypertension, 68.75% had hyperlipidemia, 43.75% were diabetic, 34.37% reported alcohol use, and 59.37% reported former or current tobacco use. 15.6% had a history of prior stroke while 65.62% had coronary artery disease, 25% atrial fibrillation, 43.75% heart failure, and 28.12% with valvular disease. Of this cohort, only atrial fibrillation (p-value = 0.038) and alcohol use (p-value = 0.01) differed between those who survived and those who died.

Conclusion: The US Veteran population represents a unique cohort of individuals with a higher-than-average cardiovascular physiologic and socioeconomic risk factors rendering them susceptible to heart failure and at increased risk of cardiogenic shock. We aim to begin stratifying patients with known risk factors in an effort to mitigate adverse outcomes.

IRB: Baylor IRBH-52204, VAIRBNet-1702771-4

SHOCK8

Observational Analysis of 14-Day Hemodynamic Trends on Impella 5.5 Support at a High-Volume Implanting Center

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Background: The Impella 5.5 (I5.5) is a surgically implanted axial-flow temporary left ventricular assist device (LVAD) approved for up to 14 days of use as acute mechanical circulatory support (aMCS). The hemodynamic trends of patients supported on this device over its approved duration have not been reported. We provide an analysis of the hemodynamic trends of 137 consecutive patients supported with Impella 5.5 over 14 days.

Methods: We conducted a single center observational study including all consecutive patients with advanced heart failure or cardiogenic shock supported with the I5.5 from April 1st, 2021 through October 31st, 2023. Patients were included regardless of indication for aMCS including upgrades from intra-aortic balloon pump counterpulsation or other percutaneous LVAD to I5.5 as well as weaning from veno-arterial extracorporeal membrane oxygenation with or without secondary device for left ventricular unloading. Hemodynamic trends were recorded prior to implantation, immediately after placement on ICU arrival, on day 2, day 7, and day 14. Repeated measures ANOVA and Friedman's test were used. Statistical analyses were performed using R (version 4.2.1).

Results: At baseline, patients had elevated filling pressures (right atrial pressure [RAP] 10.6±6.1 mmHg and pulmonary artery diastolic pressure [PAD] 23.3±7.8 mmHg), normal pulmonary artery pulsatility index (PAPi), and vasoactive-inotropic score of 5.0 (2.5 – 10.0). Complete hemodynamic trends are seen in the Table. Right ventricular (RV)-pulmonary artery (PA) interaction improved after Impella 5.5 placement with decreased pulmonary end arterial elastance (p<0.001) and increased pulmonary arterial compliance (p=0.025). Markers of RV function remained stable (RAP, PAPi), with some fluctuance in the RV stroke-work index. Mean PAD initially decreased and subsequently increased again after 7 days of support. Pharmacotherapeutic requirements decreased on I5.5 support evidence by decreased vasoactive-inotropic score (p<0.001).

Conclusion: Following the placement of I5.5, hemodynamic trends suggest that RV-PA coupling. There was also a reduction in VIS demonstrating improvement end-organ perfusion while being supported on I5.5. These findings overall suggest that with isolated LV support, the RV function remained stable. Effective left ventricular unloading may not be achieved with the I5.5 evidenced by the PAD trend.

Table 1. Hemodynamic Trends on Impella 5.5 Support

	Pre-impella (N = 137)	Post-impella (N = 137)	Day 7 (N = 130)	Day 7 (N = 130)	Day 14 (N = 71)	P-value
Age (mean) [n]	62.3 (32)	62.3 (32)	62.3 (30)	62.3 (30)	62.3 (15)	0.98
Weight (mean) [n]	81.5 (32)	81.5 (32)	81.5 (30)	81.5 (30)	81.5 (15)	0.624
PAD (mean) [n]	23.3 (32)	23.3 (32)	23.3 (30)	23.3 (30)	23.3 (15)	0.002
PAPi (mean) [n]	1.0 (32)	1.0 (32)	1.0 (30)	1.0 (30)	1.0 (15)	0.94
SVI (mean) [n]	35.0 (32)	35.0 (32)	35.0 (30)	35.0 (30)	35.0 (15)	0.95
EC (mean) [n]	0.77 (32)	0.77 (32)	0.77 (30)	0.77 (30)	0.77 (15)	0.005
Pre-impella (N = 137)	0.77 (32)	0.77 (32)	0.77 (30)	0.77 (30)	0.77 (15)	0.005
RVSWI (mean) [n]	0.15 (32)	0.15 (32)	0.15 (30)	0.15 (30)	0.15 (15)	0.025
VIS (n)	5.0 (32)	5.0 (32)	5.0 (30)	5.0 (30)	5.0 (15)	0.005

EC: endocardial pressure, PAPi: pulmonary artery pressure index, SVI: stroke volume index, RVSWI: right ventricular stroke work index, VIS: vasoactive-inotropic score. P-values calculated with analysis of variance or chi-square test.

SHOCK9

A Case Report of Unusual Differential Hypoxia

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Background: Patients with ARDS on femoral VA ECMO are at high risk for differential hypoxia. Hypoxic blood from the native heart/lungs meets oxygen rich blood flowing retrograde up the aorta forming a mixing point. It has two named clinical manifestations: harlequin syndrome (mixing between innominate and left carotid with right face cyanosis) and north-south syndrome (mixing post left subclavian with upper body cyanosis). Right arm arterial lines are most sensitive at identifying this phenomenon given their proximal source on the aortic arch, the innominate artery.

Methods: We describe a case of differential hypoxia in a patient with post drowning ARDS on femoral VA ECMO, that was not apparent on blood gases obtained from the right arm, as the mixing point was proximal to the innominate. We propose calling this, "silent differential hypoxia." The patient developed bradycardia and ultimately progressed to asystole. Hypoxic blood was detectable in the aortic root on blood gases obtained from a subclavian central line which inadvertently had been placed in the subclavian artery with its tip positioned in the aortic root.

Results: An 18-year-old male was presented to the ER after drowning in a river. On scene he was in PEA and required 3 rounds of CPR and intubation with ROSC in the field. In the ER he had severe refractory hypoxemia despite a high peep and FiO2. His CXR was notable for severe bilateral opacifications consistent with ARDS. CT surgery was consulted for ECMO. A left subclavian central line was placed given presence of a cervical collar. CT surgery arrived and given escalating pressors needs placed the patient on femoral VA ECMO. He was transferred to the regional ECMO center. On CXR the left subclavian central line was noted to be malpositioned in the subclavian artery. Despite an epinephrine drip his pulsatility remained <10 while flowing 3.5 LPM. Echo was notable for severe LV failure and global hypokinesis. The right radial arterial line PaO2 was 483, his post oxygenator PaO2 was 550. The PaO2 in the aortic root, obtained from the malpositioned subclavian line, was 19. With peep optimization and inhaled epoprostenols the aortic root PaO2 improved to 53. The right radial arterial line PaO2 remained >400. Conversion to V-AV ECMO was considered, however, given lack of brainstem reflexes and an isoelectric ECG, decision was made not to escalate. The patient entered a bradycardic rhythm and subsequently went asystolic. Death was declared and the circuit clamped.

Conclusion: When LV ejection is severely impaired the mixing point may be proximal to the brachiocephalic artery exposing the coronaries to hypoxic blood that won't be detectable on blood gases obtained from the right arm. Providers should consider this in patients that despite a reassuring right arm blood gas, exhibit signs of ongoing cardiac ischemia such as brady-dysrhythmias, ischemic ECG changes, or new onset systolic heart failure.



Image 1. CXR with a left subclavian central line malpositioned in the left subclavian artery with tip in the aortic root (red arrow), PA catheter malpositioned with tip at the RA-IVC junction near the inflow of the venous drainage cannula (blue arrow), and a left hemothorax (green arrow).

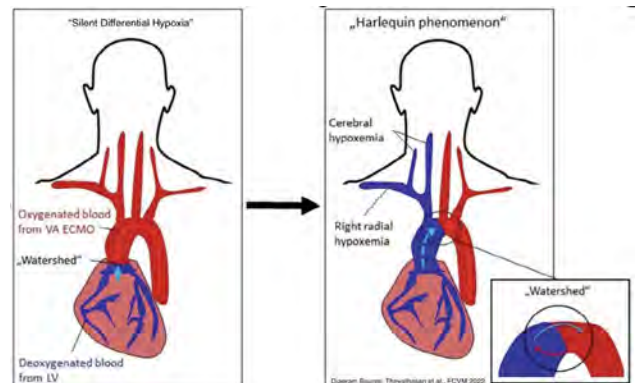


Image 2. Schematic of differential hypoxia mixing zones and resultant clinical manifestations. A. Proximal to innominate -> silent differential hypoxia. B. Between innominate and left carotid -> harlequin syndrome.

SHOCK10

Laparoscopic Abdominal Surgery in Advanced Heart Failure Patients Under Temporary Mechanical Circulatory Support

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Background: There has been an exponential adoption of transvalvular axial flow pumps (TVAFP) in recent years to provide temporary mechanical circulatory support (TMCS) for patients in cardiogenic shock (CS). The purpose of this study is to assess the clinical outcomes of TMCS in laparoscopic abdominal procedures on advanced heart failure (AHF) patients developing CS.

Methods: A retrospective review of prospectively collected data was conducted to identify patients on CS undergoing laparoscopic abdominal surgery while receiving TMCS with TVAFP. The cohort was reviewed for general demographics, cardiovascular comorbidities, CS stage on admission, type of TVAFP, inotrope requirement, type of laparoscopic surgery performed, perioperative hemodynamics, TMCS goal/trajectory, time on support, device related complications, and survival rates. To assess changes in perioperative hemodynamics, an ANOVA test was performed to compare logged values prior-to, during, and following surgery.

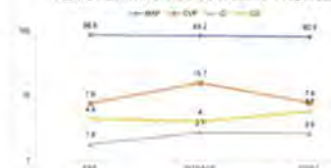
Results: A total of 8 patients were identified for analysis. The cohort was predominantly male (63%) with a mean age of 46.3±18.4-years. The most common etiology of AHF was non-ischemic cardiomyopathy (75%), with most patients admitted in CS SCAI Stage C (86%). The most utilized inotropic support was vasopressin (75%). Laparoscopic sleeve gastrectomy was the most frequent abdominal surgery (62.5%), with additional procedures including adrenalectomy, salpingo-oophorectomy, and cholecystectomy. Seven patients (87.5%) remained hemodynamically stable through the operation, and 1 patient required escalation of support to VA ECMO due to progression of cardiogenic shock (SCAI E). Table 1 summarizes TMCS goal/trajectory and postoperative outcomes. No device related complications were reported, and hospital survival was 100%.

Conclusions: Our initial observations reveal that laparoscopic surgeries can be safely performed on cardiogenic shock patients stabilized on TVAFP. Pneumoperitoneum below 15 mmHg does not significantly affect intraoperative hemodynamics on patients receiving TVAFP support. A low threshold for escalation of support is warranted for patients developing progressive cardiogenic shock.

Table 1 Demographics, Clinical and Surgical Characteristics		Table 2 TMCS Characteristics & Outcomes	
	Mean±SD or N (%)		Mean±SD or AVG (%)
N = 8		N = 8	
Age (years)	46.3±18.4	LOS (days)	36.8±25.2
Gender (M)	5 (63%)	OR time (minutes)	230.9±97.6
Etiology		Type of TMCS	
Non-ischemic	6 (75%)	Impella CP	3 (37.5%)
Ischemic	2 (25%)	Impella 5.5	5 (62.5%)
SCAI Stage prior to TMCS		Sodium bicarbonate line purge	6 (100%)
SCAI C	6 (86%)	Time on support (days)	14.5 (Range 2 to 55)
SCAI D	1 (14%)	TVAFP complications	0 (0%)
SCAI E	1 (14%)	Required escalation of support VA-ECMO	1 (13%)
NYHA Classification		Successful wean off support	5 (100%)
III	6 (75%)	Viewed off TVAFP	5 (62.5%)
IV	2 (25%)	OT	2 (25%)
Major Comorbidities		BMIS to re-intubate (days)	19.5±2.1
HTN	3 (38%)	BTI	4 (50%)
T2DM	5 (63%)	BMIS to listing (days)	11.2±11.0
CAO	3 (38%)	BMIS to transplant (days)	196.5±179.0
CVA	1 (13%)	OHT	3 (38%)
AKI (at initiation of TMCS)	1 (13%)	OHT & Kidney transplant	1 (13%)
CKD	1 (13%)	Listing to transplant (days)	35.7±26.6
Inotropic Support		Discharged alive	7 (88%)
Epi/epinephrine	5 (63%)	Follow-up (days)	455.1±151.3
Norepinephrine	4 (50%)	LOS (Length of stay, OR: Operative room, TMCS: Temporary mechanical circulatory support, OT: Outpatient therapy, BTI: Inpatient of Intensive Care Unit, BMIS: Bridge to Intensive Support, OHT: Outpatient heart transplant)	
Midodrine	5 (63%)		
Phenylephrine	1 (13%)		
Vasopressin	6 (75%)		
Dobutamine	2 (25%)		
Femoral AAD prior to TVAFP	4 (50%)		
Type of laparoscopic surgery			
Sleeve gastrectomy	5 (63%)		
Right Adrenalectomy	1 (13%)		
Cholecystectomy	1 (13%)		
Elective salpingo-oophorectomy	1 (13%)		

SCAI: Society for Cardiovascular Angiography & Interventions, LOS: Length of stay, OT: Operative room, TMCS: Temporary mechanical circulatory support, OT: Outpatient therapy, BTI: Inpatient of Intensive Care Unit, BMIS: Bridge to Intensive Support, OHT: Outpatient heart transplant

PERIOPERATIVE HEMODYNAMIC PROFILE



SHOCK11

Novel Use Of Newer Intravascular Ambulatory Left Ventricular Assist Devices As A Bridging Strategy For Cardiogenic Shock

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Background: Cardiogenic shock (CS), either de-novo or post-cardiotomy [PCCS] is associated with high mortality. Suitable patients maybe successfully bridged using newer intravascular ambulatory left-ventricular assist devices [LVAD] [Impella 5.5, Abiomed, Danvers, MA], facilitating mobilization and preservation of muscle mass, while awaiting determination of definitive therapy or recovery from PCCS. We compared our outcomes in three categories of patients bridged with Impella 5.5.

Methods: Between January 2020 & June 2023, 92 patients underwent trans right-axillary artery placement of LV-Impella 5.5 for cardiogenic shock. Data was collected prospectively and analyzed retrospectively. Normally distributed data was reported as means and standard deviations, using the analysis of variance [ANOVA] for differences between groups. Variables with P<0.1 were entered into a multivariable logistic regression model to identify predictors of hospital mortality, and reported as odds ratios [OR]. Survival data was plotted by the Kaplan-Meier method, using the log-rank test for differences between groups. Variables with P<0.1 were entered into a multivariable Cox regression model to identify predictors of late mortality, and the data was reported as hazard ratios [HR]. P<0.05 denoted statistical significance across all analyses.

Results: Mean age was 59±13years. The entire cohort was divided into 3 groups; group-1: 24 patients receiving durable LVAD, group-2: 28 patients receiving transplant, group-3: 36 patients for PCCS. In 4 patients it was placed as bridge to decision and these were excluded from analyses, as they did not receive definitive therapy.

Complications included Impella malfunction in 5 patients, axillary hematoma in 6 patients, GI bleed in 9 patients, stroke in 5 patients, HIT in 4 patients, and hemodialysis in 12 patients.

During the index hospital admission 12 patients died [13%]. Based on univariate model, variables with p<0.1 were entered into a logistic regression model to identify predictors of perioperative mortality; interestingly, none of these variables achieved statistical significance [table-1].

Patients were followed for 17±13 months. At 2 years, actuarial survival was 75±10% in LVAD group, 89±6% in transplant group, and 58±9% in PCCS group [Figure, P=0.02]. Based on univariate Kaplan-Meier model, variables with p<0.1 were entered into a multivariate Cox proportional hazards model; interestingly, none of these variables were statistically significant [table-2].

Conclusions: Our cohort includes a diverse patient population undergoing newer intravascular ambulatory LVAD [Impella] 5.5 placement as a bridge to definitive therapy, and demonstrates low rate of adverse events combined with excellent survival. Importantly, it has significantly reduced our ECMO usage for planned high-risk cardiac surgery. Furthermore, in the transplant cohort, it has greatly facilitated early ambulation whilst awaiting a suitable heart as Status 2 on the waiting list.

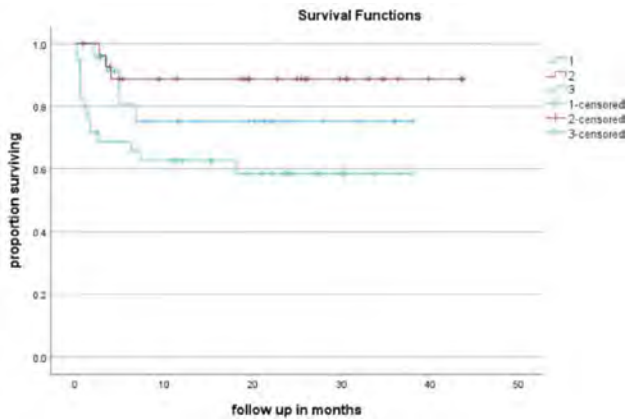


Figure 1. Survival by categories of Impella 5.5

Group-1 durable left ventricular assist device
Group-2 transplant
Group-3 post cardiectomy support.

Table-1: Predictors of hospital-mortality

Variable	Odds ratio	95% confidence interval	P-value
RVAD	1.170	0.16-8.4	.876
Age in years	1.029	0.96-1.1	.433
Diabetes	.614	0.11-3.5	.583
Hypertension	1.301	0.15-11.6	.814
Hyperlipidemia	3.274	0.56-19.0	.187
Coronary artery disease	.395	0.02-6.9	.524
Peripheral vascular disease	.953	0.07-12.9	.971
Myocardial infarction	2.748	0.24-31.4	.416

Table-2: Predictors of long-term mortality

Variable	Hazards ratio	95% confidence interval	P-value
Impella category	.495	0.12-2.1	.339
RVAD	1.792	0.44-7.2	.413
Gastrointestinal bleed	1.776	0.34-9.3	.496
Dialysis	1.454	0.42-5.1	.559
Age in years	1.018	0.98-1.07	.530
Hypertension	2.457	0.74-8.13	.141
COPD	.823	0.17-3.9	.806
Hyperlipidemia	1.615	0.4-6.46	.498
Coronary artery disease	1.259	0.24-6.6	.785
Peripheral vascular disease	3.769	0.73-19.4	.113
Myocardial infarction	.553	0.12-2.54	.446
Intra-aortic balloon pump	3.348	0.75-14.9	.113
ECMO	1.988	0.65-6.11	.231

SHOCK12

Outcomes of Left Atrial Veno-Arterial (LAVA) Extracorporeal Membrane Oxygenation Case Series: A Single-Center Experience

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Background: Extracorporeal membrane oxygenation (ECMO) has revolutionized the treatment of refractory cardiac and respiratory failure. ECMO provides hemodynamic stability and adequate end-organ perfusion in patients with refractory cardiogenic shock. A concession of using femoral veno-arterial ECMO is it can increase the afterload on the left ventricle (LV) thus causing ventricular distention, myocardial ischemia, and pulmonary edema. Therefore, some situations require venting the LV for decompression and myocardium recovery. Left atrial veno-arterial (LAVA) ECMO is a growing option that potentially closes this gap in ECMO coverage. Here, we aim to establish the outcomes and potential limitations of LAVA ECMO.

Methods: A retrospective review of all patients requiring ECMO and a transeptal cannula being placed at our institution between January 1 of 2020 and December 21 of 2022 was conducted. Demographics, indications and intent for ECMO, approach, transeptal cannula type, mortality, and post-procedural events were collected.

Results: Seventeen patients required ECMO and a transeptal cannula being placed during this study period. Of these, 12 patients had a transeptal multistage venous cannula placed for cardiogenic shock that met the criteria for LAVA ECMO and were included for analysis. Mean age was 43.1 ± 14.2 years old and ECMO run duration range from 2-35 days with a median of 8.5 days. LAVA ECMO was required in 66.6% (n=2) patients intended as a bridge-to-transplant (BTT), 16.7% (n=2) patients intended as a bridge-to-recovery (BTR), and 16.7% (n=2) patients intended as a bridge-to-LVAD (BTLVAD). No Impella devices were used while patients were on LAVA ECMO, but 1 intra-aortic balloon pump was in place before LAVA ECMO cannulation and was subsequently removed < 24 hours after LAVA ECMO was initiated. No patients developed pulmonary edema or had cannula dislodgment to the right atrium. All patients were ambulating while on ECMO. The most common complications include infection (n=3), vascular repair of cannulation site (n=2), continuous renal replacement therapy use (n=2), and limb ischemia (n=2). The in-hospital mortality rate for BTR patients was 100% (2/2), BTT patients was 12.5% (1/8), and BTLVAD patients was 0% (0/2).

Conclusion: LAVA ECMO allows simultaneous venous drainage and LV venting which allows for less devices being used at once and appears to be safe and effective. LAVA ECMO should be considered in cardiogenic shock patients that are candidates for BTT or BTLVAD but should be cautiously considered if intended for BTR. Future studies should be aimed at establishing more specific criteria for patient selection.

P1

The Use of Micro-CT Imaging Techniques to Establish Safety of a Synthetic Vascular Graft

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Introduction: Current standard practices in preclinical medical device histopathological evaluation involve examination of micron-thick sections of device and surrounding tissue under a microscope. Alternatively, micro-CT imaging offers a nondestructive method for pathological evaluation of medical devices. In the setting of vascular grafts, micro-CT allows for cohesive 3D visualization of the vessel lumen not possible through histology. The goal of this study involved evaluating the safety of a novel polyester synthetically sealed graft™ (SSG) (Diaxamed, Greenville, SC) in an ovine model.

Methods: 18 sheep were implanted with either a control (n = 5; Vascutek Tereumo Gelweave™ Vascular Prosthesis) or test article (n = 13; Diaxamed SSG polyester graft™) in the descending thoracic aorta. Devices were explanted at time points of 30, 90, and 180 days. All devices and surrounding tissue were micro-CT scanned and reconstructed using the NSI X50 X-ray/CT system. 3D cross sections were analyzed to assess pseudointimal formation on the graft surface. Segmentation was performed in 3D Slicer to create 3D lumen volumes of the graft, proximal and distal anastomosis sites, and proximal and distal aorta.

Results: From micro-CT, all devices, both test and control, have a patent lumen. Irregular lumen surface topography was identified by the presence of indented regions in 3D segmented volumes produced for all devices. Control devices at 180 days exhibited the most pronounced differences. Test devices at 180 days show ridges of the graft; however, prominent smooth areas on the lumen surface when compared to test devices at 30 and 90 days indicate advanced, but incomplete, pseudointimal deposition occurring at later time points.

Conclusion: Histological evaluation inhibits a cohesive evaluation of device efficacy introducing processing artifacts and compromising the integrity of the device and surrounding tissue. Micro-CT allowed for an accurate preview of graft morphology and provided a non-invasive method of examining graft structure and pseudointimal formation. Integration of micro-CT with histological techniques enables a comprehensive evaluation of the safety of implanted grafts. This accommodates confirmation of lumen patency that would be challenging otherwise.



Figures 1A and 1B. Micro-CT cross-section images of proximal test and control device lumen at 180-day time point.

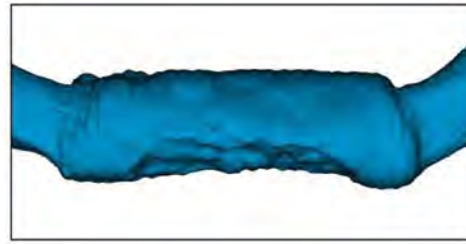


Figure 2A. 180-day segmentation image of control article lumen.



Figure 2B. 30-day segmentation image of test article lumen.

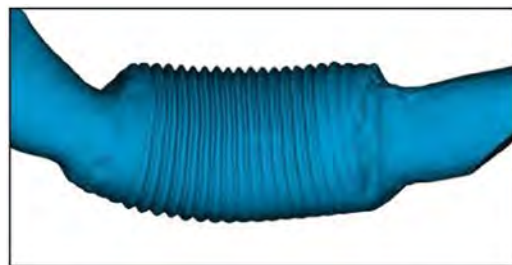


Figure 2C. 90-day segmentation image of test article lumen.

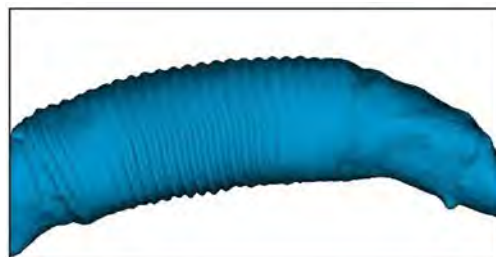


Figure 2D. 180-day segmentation image of test article lumen.

P2

Acute *In Vivo* Studies to Develop a Large Animal Model Simulating Diastolic Heart Failure

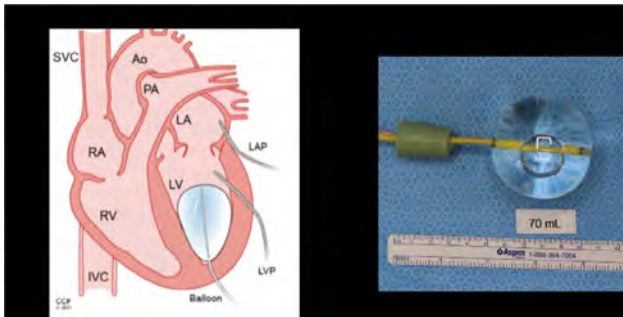
Chihiro Miyagi, Taiyo Kuroda, Anthony Polakowski, Christine R. Flick, Barry D. Kuban, Jamshid H. Karimov, Kiyotaka Fukamachi; *Biomedical Engineering, Cleveland Clinic Lerner Research Institute, Beachwood, Ohio, United States*

Background: Currently, the prevalence of heart failure with preserved ejection fraction (HFpEF) is increasing, and although some progress in pharmacological approaches is reported, many attempts to develop new devices specifically for HFpEF patients have not been successful. The main obstacle is a lack of large animal models that can instantly simulate diastolic heart failure (DHF), which is a representative feature of HFpEF, to effectively evaluate the device's function. We developed a novel large animal model to simulate DHF characteristics by inflating a balloon inside the left ventricle (LV) (Fig. 1A) and report the results here.

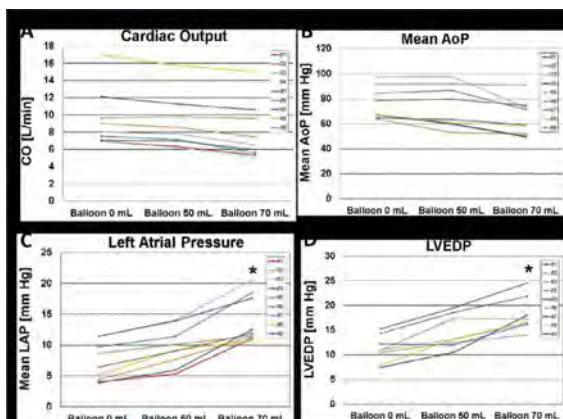
Methods: The intracardiac balloon (Fig. 1B) was implanted in nine calves ($n=9$; mean weight 87.3 ± 8.7 kg). After the left thoracotomy, the LV apex was exposed, and the balloon was inserted into the LV. It was inflated with 50 or 70 mL of saline. The hemodynamics for each balloon volume (0, 50, and 70 mL) setting were recorded.

Results: The balloon inflation caused a decrease in cardiac output (Fig. 2A) and a decrease in mean aortic pressure (Fig. 2B) ($p=ns$). The left atrial pressure significantly increased by the balloon inflation from 7.2 ± 3.1 mm Hg at 0 mL to 9.6 ± 3.1 mm Hg at 50 mL and 13.9 ± 3.8 mm Hg at 70 mL (Fig. 2C) ($p<0.001$ between 0 and 70 mL), and similarly, the LV end-diastolic pressure (LVEDP) significantly increased by the balloon inflation from 10.7 ± 2.9 mm Hg at 0 mL to 14.1 ± 3.4 mm Hg at 50 mL and 18.1 ± 3.2 mm Hg at 70 mL (Fig. 2D) ($p<0.001$ between 0 and 70 mL).

Conclusion: Although the number of animals is small, and we evaluated only acute data, this method is very simple and is a breakthrough step in establishing a new large animal model of DHF conditions. Additional studies, including chronic evaluations, are underway.



Intracardiac balloon device, A: Schematic illustration of the intracardiac balloon device inserted to and inflated in the left ventricle, B: A photo of the intracardiac balloon inflated with 70 mL of saline.



Effects of the intracardiac balloon on the healthy heart, A: cardiac output, B: arterial pressure, C: left atrial pressure, and D: left ventricular end-diastolic pressure. * $p<0.001$ between 0 and 70 mL.

P3

A Modified Dynamic Roller-pump Occlusion Setting Method to Improve Consistency for *In Vitro* Thrombogenicity Flow Loop Testing

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Purpose: For *in vitro* thrombogenicity flow loop test systems, to evaluate different samples and controls concurrently, multiple cardiopulmonary bypass (CPB) roller pumps are needed. To ensure different pumps produce similar outcomes under the same test conditions, appropriately setting the tubing occlusion in each test pump is critical. A dynamic pressure-based occlusion setting method was previously proposed by Tamari for use in clinical applications. However, this method is cumbersome and may lack accuracy for use in *in vitro* flow loop testing. Our goal was to establish a more straightforward and accurate pump occlusion setting method to minimize pump-to-pump variation.

Methods: Four CPB roller pumps from different manufacturers were used. The pump occlusion was either set per the Tamari method or the proposed modified dynamic method. For the Tamari method, a pressure monitor was attached to the outlet tubing using a three-way connector. The pump speed was set to 5 RPM and the tubing distal to the pressure monitor was clamped. The pump occlusion was increased until the average pressure reading reached 350 mmHg. For the modified dynamic method, the pump speed was set to 20 RPM to aspirate phosphate buffered saline (PBS) from an open container. The roller occlusion was increased until the PBS column reached an initial height of at least 18 cm following the first half rotation of the rollers around the pump track, after submerging the inlet tube into the PBS container, and at least 32 cm (at the inlet gate) following a full rotation (Fig 1. A). After the occlusion was set, anticoagulated bovine blood was recirculated through the flow loops containing a latex sample at 20 RPM for 1 hour at room temperature. The flow loops and test materials were visually inspected for thrombus formation and platelet count reduction was measured in the blood.

Results: The thrombus formation (Fig 1. B, C) appeared to be more consistent across the 4 pumps when using the modified dynamic method compared to the Tamari method. This difference was more clearly demonstrated in platelet count reduction results (Fig 1. E, F). For the Tamari method, the pumps produced comparable platelet count reductions (values within 10 % of each other) in only 1 out of the 5 runs. Pump consistency was improved with the modified dynamic method, with comparable platelet count reduction being produced across all pumps in 4 out of the 5 test runs.

Summary: We found that when the modified dynamic occlusion method was used, the test system was able to consistently produce similar test outcomes (thrombus deposition and platelet count reduction) for the same material and test condition across all the CPB roller pumps, despite the pumps being from different manufacturers. This method will be further investigated in an ASTM interlaboratory study to develop standardized best practices for performing *in vitro* dynamic thrombogenicity testing of medical devices and materials.

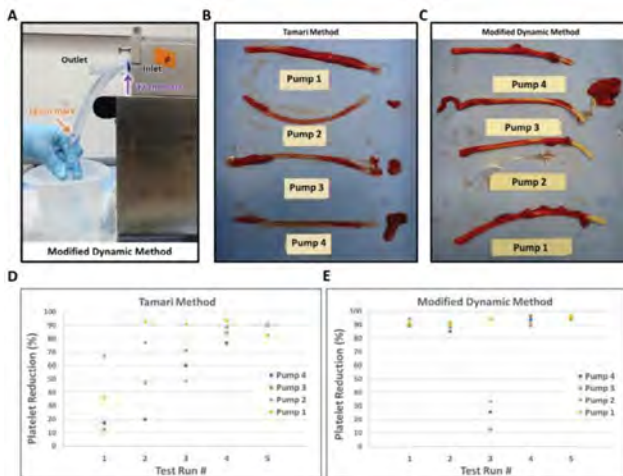


Figure 1. Images showing (A) fluid uptake height after a half (18 cm) and full (32 cm) rotation. Magnitude of thrombus formation on latex using (B) the Tamari method, and (C) the modified dynamic method for setting pump occlusion. Platelet count reduction (%) resulting from using (D) the Tamari method and (E) the modified dynamic method. For each occlusion method, 5 test runs were performed using bovine blood from 3 donors (blood from 2 donors was performed in duplicate). Duplicate runs: 1 and 2, 3 and 4).

P4

Towards individualized, 3D-printable membrane oxygenators as long-term lung support system

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Objective: Supporting blood gas exchange through extracorporeal membrane oxygenation (ECMO) is the only treatment that allows patients with severe lung failure to bridge the gap until recovery or lung transplantation (LTx). However, the duration of use of today's ECMO oxygenators with hollow fiber membranes (HFM) is limited. Irregular flow patterns and foreign surfaces inside these oxygenators often lead to the formation of blood clots and pro-inflammatory reactions, necessitating risky device replacement.

Novel oxygenators, which could enable permanent use and even implantation as an alternative to LTx, could be based on 3D-printed triple periodic minimal surfaces (TPMS) with uniform blood flow and improved gas transfer. The endothelialization of all blood-contacting surfaces with endothelial cells (EC) could protect the foreign surface from prothrombotic activators. In this study, computational fluid dynamics (CFD) of a TPMS-based prototype with the shape and size of a rat lung was simulated and compared with HFM modules of the same size. Biocompatibility tests were performed to identify 3D printable materials suitable for future studies evaluating endothelialized prototypes.

Methods: A model oxygenator consisting of TPMS structures was designed on the basis of computer tomography data. The CFD models represented 3x2x2 unit cells of TPMS and HFM. The modelling of O₂ and CO₂ gas transfer rates followed Hormes' approach. The gas transfer rate evaluation included different membrane thicknesses and flow rates at partial pressures according to DIN ISO 7199. Selected 3D printable materials (MAP-PDMS, PDMS-coated FlexaGrey, PorePro and GR-20MJF) were tested for their cytotoxicity to ECs using the WST8 assay. The adhesion affinity of platelets was tested with human platelets. EC adhesion to fibronectin-coated materials was evaluated by calcein-AM staining. Activation status of pro-thrombotic and pro-inflammatory genes was determined by qRT-PCR. Platelet confluence and basal matrix regeneration were assessed by immunofluorescence for CDH5 and collagen-IV.

Results: CFD simulations predicted uniform flow over TPMS-based oxygenator, with the exception of a slightly increased velocity in the area of the openings. In contrast to HFM, no stagnation was observed with TPMS modules. Compared to HFM, TPMS modules with 10 µm membranes outperformed the O₂ transfer rate at every simulated flow rate. PDMS-coated FlexaGrey and GR-20MJF membranes passed biocompatibility and platelet adhesion tests and enabled the cultivation of non-activated, interconnected ECs on a basement matrix.

Conclusion: Novel TPMS-based oxygenators with increased gas transfer rates and improved haemodynamics can be designed according to the patient's anatomy. The PDMS-coated materials FlexaGrey and GR-20MJF, which enable endothelialization, are suitable for 3D prototyping. These next-generation oxygenators have the potential to provide a desperately needed alternative to LTx.

P5

In-vitro evaluation of thrombogenicity of biomaterials for blood-wetted artificial organs with human blood

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Study: This study was performed to provide a comparative assessment of thrombogenicity of common blood-contacting biomaterials used in artificial organs: including Titanium alloy (Ti6Al4V), Titanium Nitride (TiN), polyether ether ketone (PEEK) varieties, and Loctite MED413. Because the ISO-10993 protocol does not include a functional test of thrombus deposition, a modified ASTM F2888-19 protocol was adopted.

Methods: The ASTM F2888-19 protocol was modified to enhance the accuracy and repeatability of thrombogenicity tests. Fresh human blood from healthy volunteers was drawn into Vacutainer tubes with sodium citrate (3.2% 0.109 M) per our IRB approved protocol. Samples were screened using a hematology analyzer to ensure normal platelet and leukocyte levels. Subsequently, the blood was pooled to reach a volume of 20 ml, lightly heparinized to a concentration of 1.2-1.5 U/mL, and then recalcified using a 2M CaCl₂ solution to achieve a concentration of 10 mM and a target activated clotting time (ACT) of 210-220 seconds, measured using the Hemochron Signature Elite system. This pooled blood was then divided into 12 polypropylene test tubes containing cylindrical samples of the candidate biomaterials (8 mm OD, 6 cm length), providing an area-to-volume ratio of 10.7 cm²/mL, as shown in Figure 1. Samples were then incubated for 1 hour at 37°C with gentle agitation.

Results: Thrombogenicity was assessed by measuring the percent reduction in platelet count in blood and visually inspecting the samples for adherent thrombi. Using the ASTM-recommended dosage of heparin and CaCl₂ corresponding to an ACT over 260 s did not yield observable thrombi on any of the samples, including the positive control. However, titrating the ACT to the range of 210-220 seconds fulfilled both the positive and negative control requirements and facilitated differentiation between the tested materials: Ti6Al4V, TiN, several PEEK varieties, and Loctite MED413. The outcome of these tests will inform the biomaterial selection for the blood flow path of a pediatric ventricular assist device developed by our group.

Conclusion: The ASTM F2888-19 protocol with human blood, titrated to an ACT of 210-220 s, offers a simple benchtop assay for comparative testing of thrombogenicity of blood-wetted biomaterials.

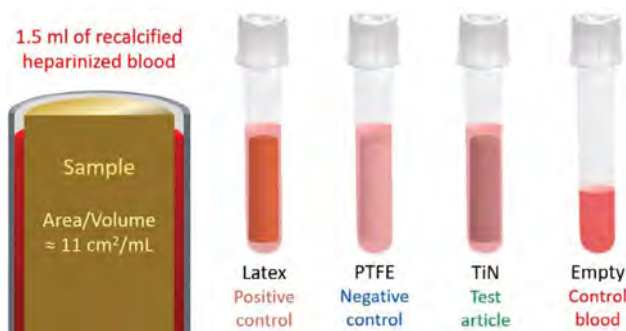


Figure 1. Cylindrical material samples were incubated in whole human blood for 1 hour. Donor blood was citrated upon collection, then heparinized and recalcified before a test to an ACT of 210-220 s.

P6

Molecular Insight into the Mechanism of Pulmonary Vein Stenosis in Pediatric Patients

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Background: Pediatric pulmonary vein stenosis (PVS) is a rare, poorly understood disease process associated with high recurrence, morbidity, and mortality. Obstructive neo-intimal lesions in the pulmonary veins can lead to pulmonary hypertension and right heart failure, necessitating intensive surveillance, multimodal therapy, and multiple interventions. Recurrent phenotype is common in PVS patients, which require multiple interventions. This study is designed to address this challenge and understand the underlying molecular mechanism for recurrent PVS.

Methods: Following IRB approval, pulmonary vein tissue was collected from the Biorepository. In total, 4 pulmonary vein samples were obtained from 4 unique patients, 2 each from nonrecurrent and recurrent PVS patients. Recurrent phenotype was defined as having two or more catheter or operative interventions for PVS within a one-year interval. A TRIzol™ based protocol was used to isolate total RNA and samples with A260/A280 ratio of 1.8-2.0 and A230/280 less than 1.6 were used. Purified RNA samples were shipped to Novogene Inc for bulk RNA sequencing.

Results: All the sequencing reads were close to 100%, demonstrating the high quality of all samples (Figure 1A). There were 2283 upregulated genes, 3477 downregulated genes and 20948 genes with no change (Figure 1B). Based on gene ontology analysis, significant changes were noted in energy metabolism, cellular respiration, muscle cell development, ATP metabolism and striated muscle contraction (Figure 1C). These results were consistent with the KEGG analysis, showing significant changes in energy metabolism, respiration and muscle contraction (Figure 1D). Calcium handling (Figure 1E) and cardiac muscle contraction, both known to be important in cardiac muscle contraction, showed nodes with significant changes in the expression of specific genes (Figure 1F).

Summary: Our results demonstrate that recurrent PVS is due to changes in the gene expression of pulmonary vein tissue. Multiple targets have been identified, some of which affect calcium handling and heart muscle contraction and can explain right heart failure in recurrent PVS patients. Further validation of these targets and testing in an animal model can lead to the development of potential therapies to treat recurrent PVS.

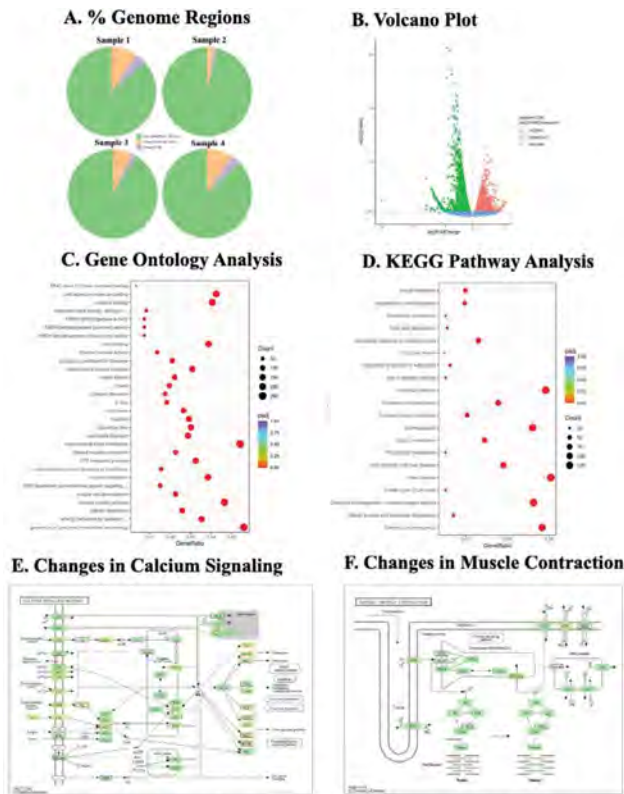


Figure 1 – Changes in Gene Profile of Recurrent vs Nonrecurrent PVS Phenotype. A shows the % genome reads. B shows the number of differentially expressed genes. C&D shows gene ontology analysis and KEGG analysis, respectively. E&F shows changes in specific genes that regulate calcium signaling and muscle contraction, respectively.

P7

Use of Low Vacuum Scanning Electron Microscopy (LVSEM) for Evaluation of a Synthetic Vascular Graft

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Introduction: In this study, the performance of a new synthetic graft (Dixamed SSG Polyester Graft™) was assessed within an ovine aortic graft model. With these types of implantable devices, assessment of level and extent of endothelialization of the blood-contacting surface is an important component of determining the device biocompatibility. Although fully endothelialized surfaces are often grossly evident, and will generally present grossly as a white opaque appearance, surfaces that are actively undergoing remodeling may be more difficult to assess grossly. While histopathologic analysis can aid in this assessment, this technique is limited due to sectioning artifacts that can come when sectioning this delicate interface. Low vacuum scanning electron microscopy (LVSEM) offers a nondestructive method for surface evaluation that can be integrated with histology to provide enhanced insights for determining the host response to the device.

Methods: The synthetic graft was implanted in the aortic position in 18 specimens and implanted for 30, 90, and 180 days. After explantation of the device and fixation with formalin, sections of the proximal and distal anastomoses were dehydrated in graded alcohol solutions and imaged with a Hitachi TM3000 Tabletop Scanning Electron Microscope™. The anastomoses between the graft and the native aorta were visually assessed for the topographical transition of neointima of the aorta to pseudointimal covering of the graft surface. Additionally, the LVSEM images were used to evaluate suture site dehiscence and mural thrombus formation.

Results: The LVSEM offered a more complete analysis of the device anastomoses regions which were difficult to assess with paraffin histology (due to sectioning artifacts). As the implant duration increased, the level of endothelialization increased.

Conclusion: Due to the nature of histological processing, there may be sectioning artifacts in traditional paraffin histology sections that preclude complete analysis of this blood-contacting surface. These artifacts can inhibit interpretation of the host aorta and graft interaction and healing phases at the anastomosis sites. Low vacuum scanning electron microscopy allows for a more robust assessment of the blood-contacting surface and can enhance interpretation of the host response and overall healing response of the device.

P10

Patient-Specific Hemodynamic Modeling to Optimize LVAD Speed and Right Heart Health

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Background: LVAD speed optimization is essential for efficient LVAD therapy and to minimize complications. However, the ideal LVAD speed is unknown and must be tailored for each patient. The interplay between the LVAD, systemic and pulmonary circulations is critical and should be considered during optimization. A computational hemodynamic model that can be tailored for each patient may provide clinicians with useful guidance and reduce the need for repeated invasive studies. This study sought to customize and evaluate a patient-specific LVAD hemodynamic optimization model.

Methods: We conducted a retrospective analysis on 25 patients implanted with HM3 and who underwent right heart catheterization (RHC) outpatient titration at University of Florida. A custom designed computational hemodynamic lumped parameter model (HLPm) was developed consisting of 27 equation differential algebraic expression modeling with more than 50 customizable physiological parameters. The HM3 pressure-flow curves were incorporated and the HLPm was customized for each patient based on their systemic and pulmonary resistance parameters. Each patient-specific model was evaluated independently for optimizing LVAD speed based on mean arterial pressure (MAP) targets ranging from 70-90 mmHg. The optimized HLPm model was compared to RHC data and clinician guided speed optimization.

Results: 16 patients met analysis criteria, with a median age of 63 years, 69% male and 75% white. 69% were implanted as destination therapy, with a median baseline speed of 5100 rpm. 16 customized patient-specific models were successfully obtained. To achieve a target MAP of 70 mmHg, the HLPm predicted LVAD speed reduction for 14 patients (87.5%), with a median speed reduction of 275 rpm. For a target MAP of 80 mmHg, HLPm predicted speed reduction for 10 patients (62.5%) and a median speed reduction of 230 rpm (Figure 1b). For the highest target MAP of 90 mmHg, the HLPm predicted a speed reduction for 6 patients (37.5%), with a median speed reduction of 115 rpm (Figure 1c). Compared to the clinical guided speed optimization, the HLPm suggested a speed reduction in 10 patients (62.5%), with a median reduction of 160 rpm and a median speed increase of 175 rpm for the remaining 6 patients (Figure 1a). Finally, the HLPm indicated that speed optimization would shift the pulmonary artery pressure ranges towards the healthy range (i.e.30 mmHg) for 14 patients (87.5%) (Figure 1d).

Conclusions: Overall, there was congruence between HLPm predictions and RHC and clinician guided speed optimization, with a median difference of 40 rpm. However, magnitude of speed change varied. The patient-specific HLPm provides a valuable option for clinicians to evaluate LVAD speed titration changes, including analysis of pulmonary system parameters to avoid right heart overload. Future studies will include further customization of model parameters and prospective comparison for improved LVAD speed optimization predictions.

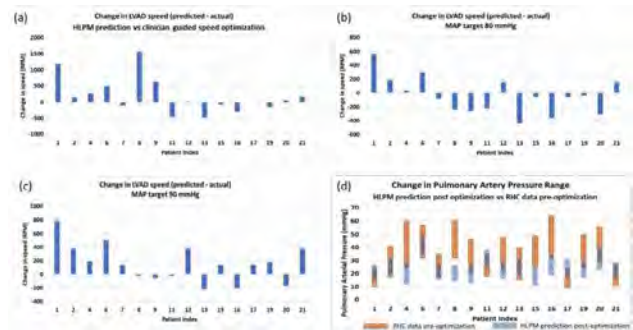


Figure 1: (a) HLPm-predicted change in LVAD speed compared to actual clinician guided optimization (b) HLPm-predicted change in LVAD speed for MAP target of 80 mmHg indicating more overall speed decrease (c) HLPm-predicted change in LVAD speed for MAP target of 90 mmHg indicating more overall speed increase (d) comparison of pulmonary artery pressure range between RHC measured data pre-optimization (orange) and after HLPm-predicted LVAD speed optimization change (blue)

Figure 1. (a) HLPm-predicted change in LVAD speed compared to actual clinician guided optimization (b) HLPm-predicted change in LVAD speed for MAP target of 80 mmHg indicating more overall speed decrease (c) HLPm-predicted change in LVAD speed for MAP target of 90 mmHg indicating more overall speed increase (d) comparison of pulmonary artery pressure range between RHC measured data pre-optimization (orange) and after HLPm-predicted LVAD speed optimization change (blue)

P11

Modulated electrical stimulation to treat dysphagia

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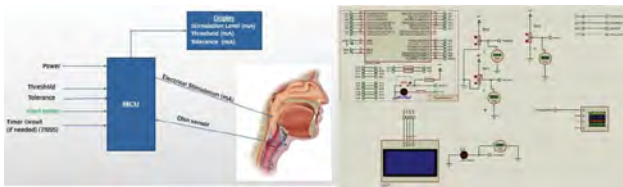
Background: Dysphagia following stroke and post extubation phase is a debilitating condition with limited interventional options. This in turn impacts pulmonary care, nutritional needs, and prolongs hospitalization. X-phagia is an innovative device which uses an exoskeleton tube advanced (over a feeding tube) into the posterior pharynx and stimulated using electrical energy with an external chin-based sensor acting as an efficacy control.

Methodology: The X-phagia device operates at a frequency of 3Hz, utilizing a pulse width of 300µs. The controlled current range, based on stimulation level calculations, spans from 1mA to 20mA. Employing a square wave waveform, the device adheres to a 10-minute per session duration. With an input voltage of 5V, the device is powered by a 9V DC battery and is governed by an Atmega 328p microcontroller. The controlled threshold and tolerance range for current modulation are maintained between 1mA and 20mA.

The X-phagia device's unique feature lies in its ability to precisely modulate the current within a controlled threshold and tolerance range (1mA-20mA). This ensures patient safety and allows for personalized treatment based on individual needs. The integration of an exoskeleton and an external chin-based sensor ensures targeted and controlled stimulation. The exoskeleton (over an existing feeding tube) precisely positions the electrodes in the posterior pharynx, while the chin sensor provides real-time feedback on the efficacy of the stimulation, allowing for adjustments as needed.

Results: Initial testing of the X-phagia device demonstrates its effectiveness in delivering set current at predefined frequency. Bench top experimentation was tested in a phantom model with positive feedback with 97% accuracy. Frequency sweep and current modulation shows most optimum functioning in 5 to 12 mA range. Current decay was consistently in the sensor field with efficacy (>90%) of sensor in repeated operations (n=50)

Conclusion: The X-phagia device with repeatability and consistency may prove to be a promising intervention for managing dysphagia associated with stroke and post extubation phase. Its ability to precisely modulate current within the established threshold and tolerance range, along with the integration of an exoskeleton and external chin-based sensor, facilitates targeted and controlled stimulation.



X-phagia Device

P12

Complications Associated with Percutaneous Pulmonary Artery Cannulas: a Retrospective Analysis

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Right ventricular dysfunction (RVD) and failure (RVF) can result from various etiologies, including intrinsic and secondary causes like left heart failure, ischemia, and respiratory failure. RVF strategies have traditionally focused on medical management and left heart support, however the advent of percutaneous pulmonary arterial (PA) cannulas have broadened RV mechanical support options. In refractory RVF, temporary right ventricular assist device (RVAD) can be implemented with a PA cannula inserted via the internal jugular or subclavian vein. This can be paired with an oxygenator for veno-pulmonary extracorporeal membrane oxygenator (VP-ECMO) support. Known complications associated with percutaneous PA cannulas include bleeding, acute kidney injury, and thromboembolic events, however, studies to date have been limited. In this analysis, we present complications associated with percutaneous PA cannula implantation, maintenance and decannulation.

Records of 25 patients who underwent percutaneous PA cannula support were searched using keywords related to a list of possible complications selected by investigators. Complications were classified as related to implantation, maintenance, or decannulation.

In this 25-patient cohort, median RVAD/VP ECMO support lasted 11 days (IQR 7-28). Of 134 complications, 96.3% (129/134) were maintenance related. Notably, 84% (21/25) experienced new or worsened tricuspid or pulmonic valve regurgitation, and 56% (14/25) required circuit or oxygenator exchanges. Other issues were hemolysis (36%, 9/25), bleeding (32%, 8/25), circuit consumption of coagulation factors (32%, 8/25), kidney injury (28%, 7/25), liver injury (24%, 6/25), and DVT (24%, 6/25). Less frequent were hypoxemia/desaturation events (20%, 5/25), HIT/HITT (16%, 4/25), and intracardiac thrombi (16%, 4/25). PA cannula thrombi were rare (12%, 3/25) but are a notable complication. Implantation complications were notably absent, as were most decannulation issues, except for sustained tricuspid or pulmonic valve regurgitation (16%, 4/25) and one DVT case (4%, 1/25).

This study shows percutaneous PA cannulas, while safe upon implantation, may lead to complications with maintenance, like other forms of mechanical support. Unique to PA cannulas is a higher incidence of right-side valvular regurgitation, likely related to cannula size and rigidity, which resolves upon decannulation in most patients without valve damage. Maintenance issues are expected as a result of blood-circuit interactions and critical illness. Notably, 3 patients had PA cannula thrombosis, emphasizing the need for continuous monitoring. Anticipated issues included need for circuit and oxygenator changes, which is common with mechanical support. Limitations include retrospective design, small cohort, and binary complication classification that could obscure severity and clinical impact. Further research should address refining of care protocols and support technologies.

Summary of percutaneous PA cannula use and complications for all patients and by indication for support: Complications are subdivided by time of complication, i.e. at time of implantation, during maintenance phase of support and at time of decannulation. Indications for RVAD or VP ECMO included biventricular support for durable left ventricular assist device (LVAD) implantation, VP ECMO support as bridge to lung transplantation, postoperative RV failure, cardiogenic shock and massive pulmonary embolus (PE).

	Total (n=25)	Durable LVAD (n=11)	Pre-lung transplant (n=4)	Pos toperative RV failure (n=7)	Cardiogenic shock (n=2)	Massive PE (n=1)
Median days on RVAD/ VP ECMO (IQR)	17.6 (7-28)	19.5 (9-29)	30.8 (20-45)	16.9 (8-22)	25.5 (13-38)	7
Required transfusion	22 (88%)	8 (73%)	4 (100%)	7 (100%)	2 (100%)	1 (100%)
Total Com plications	134	53	31	38	6	6
Implantation	-	-	-	-	-	-
Maintenance	129	52	30	36	6	5
Decannulation	5	1	1	2	0	1

Implantation, maintenance and decannulation complications: Summary of complications at time of PA cannula implantation, maintenance phase of RVAD/VP ECMO support, and at time of decannulation.

Complication	Number (Percentage) (n=25)
Implantation complications*	0 (0%)
Maintenance Complications	
TV or PV regurgitation	21 (84%)
Oxygenator or circuit exchange	14 (56%)
Hemolysis	9 (36%)
Bleeding	8 (32%)
Circuit consumption	8 (32%)
Acute kidney injury	7 (28%)
Liver injury	6 (24%)
DVT	6 (24%)
Hypoxemia/desaturations	5 (20%)
HIT/HITT	4 (16%)
Intracardiac thrombus	4 (16%)
PA cannula thrombus	3 (12%)
Skin breakdown	2 (8%)
Circuit thrombus	2 (8%)
Stroke (ischemic or hemorrhagic)	2 (8%)
Cannula associated bacteremia	2 (8%)
Inability to wean sedation	1 (4%)
Hypothermia	1 (4%)
Hemo/Pneumothorax	0 (0%)
Decannulation Complications	
Persistent TV or PV regurgitation	4 (16%)
Post-decannulation DVT or intracardiac thrombus	1 (4%)
TV or PV vegetation	0 (0%)
Valvular injury	0 (0%)

*Implantation complications included bleeding, guidewire complications, inability to complete cannulation or cannulation that was not hemodynamically tolerated, perforation or rupture, pleural or pericardial effusion, pericardial tamponade, pneumothorax, and valvular injury.

P13

Readmission after Left Ventricular Assist Device Implantation at a Destination Therapy Center

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Background: Left ventricular assist device (LVAD) implantation is associated with improved survival but also a high incidence of readmission. The incidence, causes, and predictors of readmission are poorly characterized, particularly in the destination therapy (DT) population. We undertook this study to characterize our experience with DT-LVAD readmissions.

Methods: We conducted a retrospective review of all primary LVAD implantations at a single, non-transplant center. Primary outcome was readmission for any reason. Multivariable linear regression was utilized to identify predictors of readmissions.

Results: From 2017-2023, 151 primary LVAD implantations were performed with 12 (7.95%) perioperative mortalities. The 139 remaining patients suffered 456 separate readmissions with a median follow up of 590 [303-1002] days and a total follow up of 270.67 patient-years for a rate of 1.68 readmissions per patient-year. 31 (22.30%) patients had zero readmissions and 30 (21.58%) had one readmission. One patient had as many as 20 readmissions. The median time to readmission was 97 [59-124] days. At 1-year, freedom from readmission was 17.92%. The most common cause of readmission was heart failure exacerbation (27.0%), major infection (17.8%), and major bleeding (13.6%; Table 1). On multivariable linear regression, increasing body mass index (BMI) (p=0.02), increased preoperative bilirubin (p=0.04), and increased follow up time (p<0.01) were predictive of the need for readmissions.

Conclusion: In conclusion, readmissions after LVAD implantation are common and can be frequent. Despite the improvement in cardiac function, heart failure exacerbation remains the most frequent reason for readmission. Increased BMI and preoperative bilirubin are associated with more frequent readmissions.

Variable	Coefficient	95% Confidence Interval	p-value
Redo sternotomy	0.78	[-0.43-2.00]	0.21
Intermacs profile 1	Reference		
Intermacs profile 2	0.69	[-0.69-2.07]	0.33
Intermacs profile 3	1.28	[-0.27-2.83]	0.11
Intermacs profile 4	-0.004	[-2.53-2.52]	0.99
BMI (per kg/m ²)	0.12	[0.02-0.22]	0.02
Creatinine (per mg/dL)	0.56	[-0.64-1.76]	0.35
Total bilirubin (per mg/dL)	0.54	[0.01-1.06]	0.04
Total follow up (per year)	0.90	[0.50-1.31]	<0.01

Table 1. Prediction of baseline and follow-up factors on the need for readmission following destination therapy left ventricular assist device implantation.

P14

The Effect of Renal Denervation in an Animal Model of Polycystic Kidney Disease

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Background: Polycystic kidney disease (PKD), a genetic condition in which renal parenchyma is replaced with non-functional cysts, with associated inflammation and glomerular loss, is a significant cause of chronic renal failure, morbidity and mortality affecting 500,000 patients in the U.S. and 7MM worldwide. To date, therapeutics aimed at limiting cyst formation and renal tissue destruction are limited. Mechanistically it has been suggested that renal innervation and sympathetic/catechol mediators may be drivers of the cystic degenerative process. In recent years renal denervation has emerged as a clinical modality to limit renal nerve function, currently used for treating hypertension. Our group has been exploring the utility of total renal denervation (TRDNx) for limiting renal cyst progression in PKD. We hypothesize that TRDNx will reduce cyst size and improve renal function in an animal of PKD treated with TRDNx compared to sham-treated animals. Here we examined the effect of total renal denervation TRDNx on renal function and cyst growth in 24-week-old PCK rats – a model of PKD.

Methods: Renal function, determined via glomerular filtration rate (GFR) and renal biomarkers (BUN and creatinine) was measured in 24-week-old male and female PCK rats as baseline. Rats then underwent TRDNx (n=13) or sham (n=15) surgery. At 30 weeks renal function was repeated, rats sacrificed, and kidney tissue collected. Cystic index (%cyst area) and glomerular fibrosis were assessed.

Results: GFR did not decrease in TRDNx animals (Wk 0: 0.63±0.10 mL/min/100gBW vs Wk 6: 0.31±0.08 mL/min/100gBW) remaining similar to baseline, yet a decline was noted in sham animals (Wk 0: 0.64±0.07 mL/min/100gBW vs Wk 6: 0.34±0.16 mL/min/100gBW, p<0.05). TRDNx decreased cystic index (5.00 ± 0.97%) compared to sham (8.55 ± 0.82%), but glomerular fibrosis was not different between groups. Additionally, biomarkers of renal function (BUN, creatinine) did not differ between groups.

Conclusions: TRDNx attenuates cystogenesis and limits renal functional decline in a rat model of PKD. These promising data support renal denervation as a potential therapeutic strategy worthy of further translational advance to the clinic for eventual human investigation and use.

P15

DCD Heart Transplant in Australia – Improvements to Retrieval & Transplant Rates

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Use of Donation after Circulatory Death (DCD) donors represents a solution to the increasing demand for donor hearts. Uptake of normothermic machine perfusion (NMP) as a means to assess viability of donor hearts following a warm ischaemic insult has allowed expansion of the donor pool. In 2014, our unit was the first to adopt this in a program. Maastricht Category III donors are typically used as withdrawal of life support (WLS) occurs in a controlled manner. Long distance procurement is key to organ retrieval in Australia with local laws and policies influencing withdrawal practices. This study examines the impact of DCD heart transplants as well as the adjustments + learning curves that have ensued over the course of the first decade of DCD heart transplant. All DCD Heart retrievals performed in Australia over the last ten years (2014-2023) were included for retrospective analysis in this study. Donors underwent a WLS protocol either in ICU, Anaesthetic bay (AB), or Operating table (OT). Donor hearts were retrieved using the Sydney Direct Procurement Protocol (DPP) and placed onto the TransMedics Organ Care System (OCS). 1.2-1.5L of donor blood is drained from the right atrium into a blood collection bag containing heparin and tirofiban at the time of organ procurement. February 2020 represents the last major change to our retrieval protocol with the addition of tirofiban to the blood collection and served as a comparison point between an initial (pre-February 2020) and a contemporary cohort (post-February 2020). Donor hearts were deemed viable for transplant if a) adequate RV contractility, and b) down-trending lactate profile was observed during the duration of NMP. 164 DCD Heart retrievals took place between 2014-2023; 6 retrievals for research purposes + 158 clinical retrievals. 79 clinical retrievals occurred in each of the initial and contemporary cohorts. The progression rate in the contemporary cohort was higher though not statistically significant (86% vs 76%). The overall transplant rate of DCD donor hearts following NMP was 77% and were significantly higher in the contemporary vs the initial cohort (84% vs 68%, p=0.03). The risk of severe primary graft dysfunction (sPGD) requiring ECMO was significantly associated with an asystolic warm ischaemic time (aWIT) of >15min (p=0.03). Withdrawal location had a significant impact on aWIT. Median aWIT was found to be significantly higher when WLS occurred in ICU compared to in AB (14 vs 12min respectively; p=0.0013). There was no significant difference in 5-year survival in recipients of DCD compared to DBD heart transplant donors during the same study period.

A decade of DCD Heart transplant in Australia has seen a significant improvement in transplant rates. Whilst withdrawal location is dictated by local policy, withdrawal in the OT/AB should be advocated as a means to reduce the aWIT and reduce rates of sPGD.

P16

Left Ventricular Assist Device Exchange Is A Good Alternative To Heart Transplant In The Current Organ Allocation System

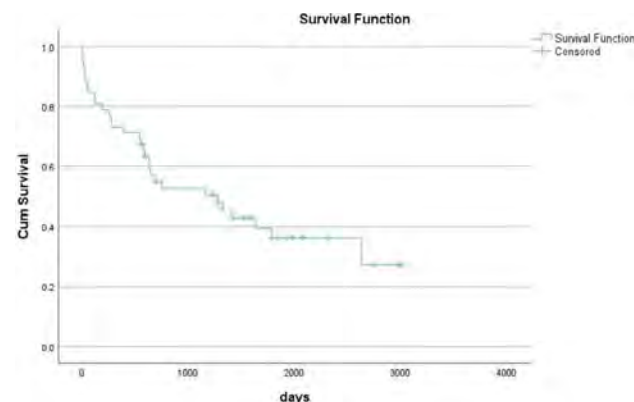
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Background: Left Ventricular Assist Device [LVAD] complications including thrombosis, infection, and driveline fractures are not infrequent and have a poor prognosis unless expeditiously managed. Heart transplant, while being a gold-standard treatment strategy for these complications, is limited by the organ allocation prioritization systems currently in place. We present our data of LVAD exchanges for device complications as a reasonable alternative to heart transplant

Methods: Between January 2010 and June 2022, 49 patients underwent LVAD exchange for device complications, amounting to 52 patient events. Approach was either redo-sternotomy, or a left subcostal incision combined with redo upper mini-sternotomy, or a left 5th space anterior mini-thoracotomy combined with redo upper mini-sternotomy. Anticoagulation was maintained per standard protocols, and included aspirin 81mg or clopidogrel 75mg in aspirin intolerant patients, and warfarin to maintain an international normalized ratio 2.5-3.5. Data were prospectively collected and retrospectively analyzed, and reported as means±standard deviations. Survival data was plotted by the Kaplan Meier method

Results: Mean age was 53±13 years. Reasons for LVAD exchange: biventricular failure requiring upgrade to total artificial heart [TAH] in 2 patients, driveline fracture in 2 patients, blood-culture positive infections in 2 patients, internal short to shield in 3 patients, TAH exchange for compression in 1 patient, and device thrombosis in the rest, as diagnosed by echocardiographic evidence of clot, rising lactate dehydrogenase and plasma-free hemoglobin. Device exchanges included Heartmate [HM] 3 to HM3 in 1 patient, HM2 to HM3 in 8 patients, HM2 to HM2 in 28 patients, HM2 to Heartware in 7 patients, Heartware to Heartware in 5 patients, and upgrade/change to TAH in 3 patients. Complications noted in the immediate postoperative period included central nervous system [CNS] ischemic stroke in 5 patients, gastrointestinal [GI] bleed in 4 patients, GI ischemia in 3 patients and long-term hemodialysis in 5 patients. Early mortality was 12% [n=6]. Actuarial survival at 5-years was 36.3±7.5%

Conclusion: LVAD exchange for device-related complications can be performed safely and effectively, and remains a good alternative to heart transplant in the current era of shortage of suitable organs



Survival pump exchange

P17

Functionality of a simplified intrapericardial extracardiac cardiac compression device

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Background: Evaluation of a novel extracardiac balloon cannula (Figure 1) for direct cardiac compression was conducted prior to initial human use. The balloon cannula is positioned anterior to the left ventricle via subxiphoid access, and its tip is anchored to the lateral aspect of the pericardium. The sternum, ribcage and spine form a rigid enclosure to provide effective cardiac compression in the antero-posterior axis. Balloon inflation is triggered by the QRS complex sensed via a subcutaneous left chest electrode. In-vitro and in-vivo studies were conducted to evaluate device safety and efficacy.

Methods: In-vitro studies were conducted on fresh porcine hearts with intact pericardial sacs and a 3D printed soft human heart. The hearts were incorporated into a 200 cm long flow circuit with a pressure transducer and an ultrasonic flow transducer placed at the aortic outflow tract. Baseline cardiac output was obtained using open heart massage at 60 bpm, while balloon inflation was performed at 60 bpm with a 180 cc, 7 cm diameter balloon. In-vivo studies were conducted on 90 kg swine with acute heart failure induced by bolus intravenous infusions of Esmolol prior to balloon inflation. Six sample readings were obtained in four animal subjects. Data from 2 first in human patients included.

Results: Balloon compression with excised porcine hearts and the 3D printed heart yielded cardiac outputs of 100 ml/min, equal to 50% of the value of open cardiac massage. In-vivo testing on Esmolol induced acute heart failure models demonstrated a mean increase in cardiac output upon balloon compression of 73.3 ± 28.1% (mean ± SD), with balloon inflation yielding a highly significant increase in cardiac output (P = 0.0026) versus baseline. The degree of increase correlated with the severity of cardiac depression. When cardiac output was reduced to 2 L/min from a baseline of 4 L/min, balloon compression normalized cardiac output to 4 L/min. Moderate Esmolol infused functional cardiac reduction of 33% led to a 50% recovery upon balloon compression. The first human clinical application of the device occurred in an 87 year old male acute myocardial infarction patient who presented with an ejection fraction of 30%. Balloon augmentation yielded a resultant EF increase to 45%. The second implant occurred in a 66 year old male on ECMO following cardiac arrest during a PCI procedure with an EF of 5%, increasing to 30% upon balloon inflation.

Conclusions: Synchronous intrapericardial extracardiac balloon assistance demonstrated effective ventricular augmentation in in-vitro and in-vivo studies, and the positive pre-clinical results were maintained upon initial human clinical application.



Figure 1.

P18

Elevated Myeloperoxidase in Heart Failure Patients with Prior History of Stroke Undergoing Left Ventricular Assist Device Implantation

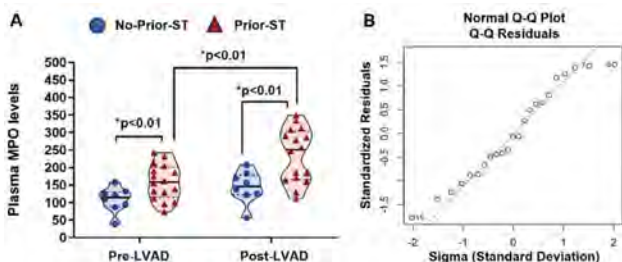
Shubh Desai¹, Jacob Scioscia¹, Ananth Panchamukhi¹, Andy Le¹, Carl Walther², Camila Hochman-Mendez³, Alexis Shafii¹, Kenneth Liao¹, Nandan Kumar Mondal¹; ¹Department of Surgery, Baylor College of Medicine, Houston, Texas, United States, ²Department of Medicine, Baylor College of Medicine, Houston, Texas, United States, ³Regenerative Medicine Research,, Texas Heart Institute, Houston, Texas, United States

Background: Left ventricular assist device (LVAD) implantation is associated with an increased risk of stroke. Systemic myeloperoxidase (MPO) was found to be linked with ischemic stroke, but it is unclear how MPO would respond to LVAD implantation and new strokes after LVAD implantation in patients with a prior stroke history. Our goal in this study was to determine baseline levels of MPO and how they change after LVAD implantation, especially in patients with prior stroke history and new onset of stroke after LVAD.

Methods: Plasma MPO level was quantified and analyzed on day 0 (pre-LVAD) and on day 7 (post-LVAD) from a subgroup of 24 HF patients. Sixteen patients had a history of stroke (Prior-ST-group) and 8 did not (No-Prior-ST-group). Data was standardized using the scale function in R and analyzed via linear regression modeling and ANOVA. A linear regression model was created using the post-LVAD MPO levels and several covariates, including pre-LVAD MPO level, age, sex, race, hypertension and smoking history at baseline, history of prior stroke, and progression of a prior stroke. A Q-Q plot was used to check whether the linear model met the normality assumption.

Results: Before LVAD implantation, patients in the Prior-ST group had significantly higher levels of MPO (158.26±12.61 vs. 108.03±12.61 pmol/L) compared to the No-Prior-ST group (p<0.01, Fig.A). After LVAD implantation, MPO levels increased in both groups, with a 63.0% increase in the Prior-ST group (p<0.01) and a 45.5% increase in the No-Prior-ST group. During the hospitalization period after LVAD implantation, one patient in the Prior-ST group experienced a new stroke after LVAD, and this patient had the highest pre-LVAD and post-LVAD MPO levels (a further 17.6% overall increase) among all patients. The points in the Q-Q plot lie approximately along a straight line, confirming the normality assumption and the reliability of its predictions (Fig.B). The model returned a multiple-adjusted R-squared value of 0.8378. Both the linear model and ANOVA demonstrated that pre-LVAD MPO levels (p<0.01) and history of stroke (p<0.01) were the only two covariates significantly associated with elevated post-LVAD MPO levels.

Conclusions: Elevated pre-LVAD MPO levels and a prior stroke significantly increased post-LVAD MPO levels, demonstrating their substantial predictive power. Patients who suffered a stroke before undergoing LVAD implantation showed elevated baseline MPO levels compared to patients without a stroke history. These patients may be at risk for higher post-LVAD MPO levels, which may further exacerbate their risk of experiencing a new stroke or the progression of an old stroke, as seen in the patients with the highest pre-LVAD and post-LVAD MPO levels. MPO might be used as a new biomarker for stroke risk after LVAD implantation. A robust study with a larger LVAD patient population with prior stroke and a longer follow-up period is warranted.



P19

Animal Experimental Study of a Displacement Sensor-Free Magnetic Levitation Ventricular Assist Device

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Background: The displacement sensor-free magnetic levitation ventricular assist device is a new magnetic levitation device developed by the team, and its key technology is to avoid the application of displacement sensing while controlling the position of the rotor accurately. The aim of this study was to investigate the operational reliability, blood compatibility, and effects on major end organs of the newly developed sensorless magnetic levitation ventricular assist system during animal experiments.

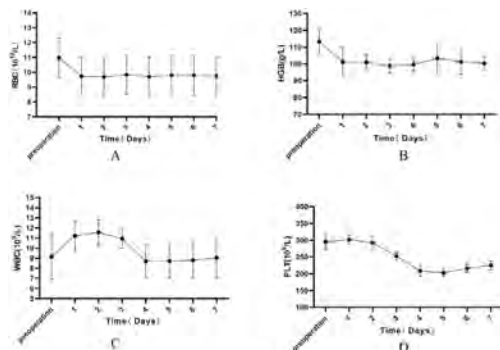
Methods: Three sheep weighing between 56.5 kg and 65.3 kg were used in this study. A magnetically levitated VAD was used to establish left heart diversion through the left atrium to the descending aorta for a 7-day animal experiment. Preoperative and postoperative daily tests included heart rate, respiratory rate, mean arterial pressure, central venous pressure, pump pressure difference, free hemoglobin, blood routine, liver and renal function, coagulation function, and inflammatory markers (e.g., IL-6, IL-8, C3a, C5a). At the end of the experiment, the organs of the animals were sampled and subjected to HE staining to observe organ embolic infarction.

Results: Three experimental sheep were successfully fitted with the self-developed magnetic levitation VAD, and the tracheal intubation was removed 2-5 h after the operation. The postoperative vital signs of the sheep were good, and the postoperative vital signs, such as heart rate, respiratory rate, mean arterial pressure, central venous pressure, and pump pressure difference, were in the normal range. The magnetic levitation pump rotated stably without abnormal noise and the pump speed was stable for 7 days after the operation. 3 sheep survived until the 7th day after the operation. free hemoglobin did not exceed 15 mg/dL within 7 days, and all the postoperative indexes, including creatinine, urea nitrogen, ALT, AST, IL-6, IL-8, C3a, and C5a indexes, basically recovered to the preoperative level. At the end stage of the experiment, no hemorrhage or infarction was observed in the organs.

Conclusion: In this study, the effectiveness and safety of the magnetic levitation ventricular assist system based on displacement-free sensors were verified through animal experiments. The experimental results showed that the system was able to effectively control the vital signs of the animals, and no serious organ damage or infarction was observed in the postoperative period, demonstrating its potential value in clinical applications.



Determination of plasma free hemoglobin during flow rotation in experimental animals



Blood routine measurement, Figure A. Trend of red blood cell changes; Figure B. Trend of hemoglobin changes, Figure C. Trend of white blood cell changes, Figure D. Trend of platelet changes

P20

Redesign of the Penn State Fontan Circulatory Assist Device

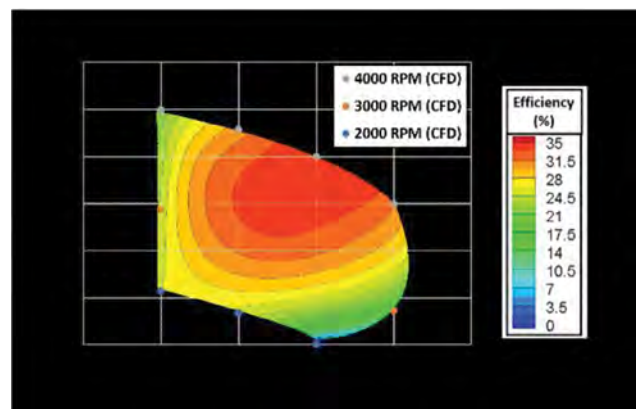
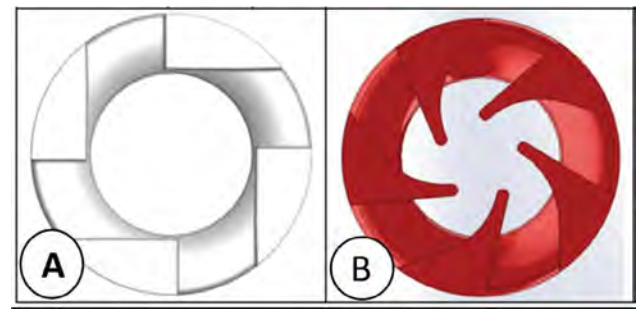
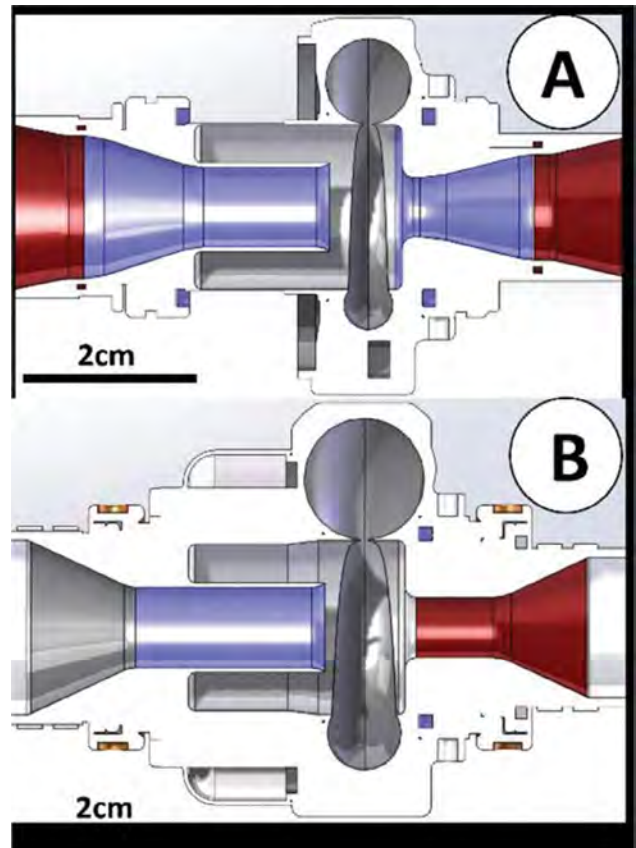
Christopher M. Scheib, Raymond Newswanger, Karl O. Bohnenberger, Joshua P. Cysyk, Branka Lukic, Eric Yeager, Patrick Leibich, Kirby Bletcher, Quandashia Jackson, Gerson Rosenberg, Choon-Sik Jhun, William J. Weiss; *Surgery, Penn State University, Hershey, Pennsylvania, United States*

Background: A series of successful 30-day in-vivo studies with the second-generation design of the Penn State Fontan Circulatory Assist Device (PSU FCAD) (Figure 1A) (2021. Cysyk et al. ASAIO J.) led our team to another clinically relevant redesign phase of the device. Clinicians determined that an increased pump outlet diameter from 12mm to 16mm would allow for an easier anastomosis to the right pulmonary artery. Since the device is intended to be fully implantable and support higher cardiac output for increased exercise tolerance, we extended the redesign phase to include our rotary impeller in an effort to improve the hydraulic performance to demand less power for the wearable batteries without sacrificing the exceptional hemodynamic performance of the device.

Methods: The in-silico exploratory redesign phase of the pump and impeller was done with Converge CFD (CONVERGE Science Inc, Madison, WI) using a Large Eddy Simulation (LES) turbulence model. All computations were executed on a Linux-based high performance computing server (System 76, Boulder, CO) containing 48 cores, 96 threads. We calculated the hydraulic efficiency of each pump design (both using the nominal rotor geometry, Figure 2A) at the target operating condition (8 LPM, pump pressure between 10 – 20 mmHg). Once the new pump geometry was determined, the rotor blade variation was conducted. The blades themselves were isolated to compute the thrombus susceptibility potential (TSP, an in-house developed strain-based model that predicts a scalar likelihood, from 0-1, of thrombus forming on a surface at any given timestep) across the final twenty time-steps of the simulation encompassing a full revolution of the rotor. Once the final design was reached, H-Q (H: pressure head, Q: flow) simulations were conducted to map the hydraulic performance of the device.

Results: The third-generation PSU FCAD outlet diameter was increased to 16mm. In order to accommodate this change, the overall axial length of the device increased by 8%, while the overall height (outermost diameter) of the device increased by 10% (Figure 1B). At the target operating condition, the new pump design improved the hydraulic efficiency by 64%. When combined with the new rotor blade design (Figure 2B), the hydraulic efficiency improved by almost a factor of two. Figure 3 shows the third-generation PSU FCAD hydraulic efficiency mapped onto the HQ results.

The final stages of the manufacturing and assembly process of the third-generation PSU FCAD are being completed, and in-vitro and 30-day in-vivo studies for hydraulic and hemodynamic performance validation are forthcoming.



P21

Pharmacogenomic Testing May be a Useful tool for Warfarin Management in Patients who Receive a Left Ventricular Assist Device

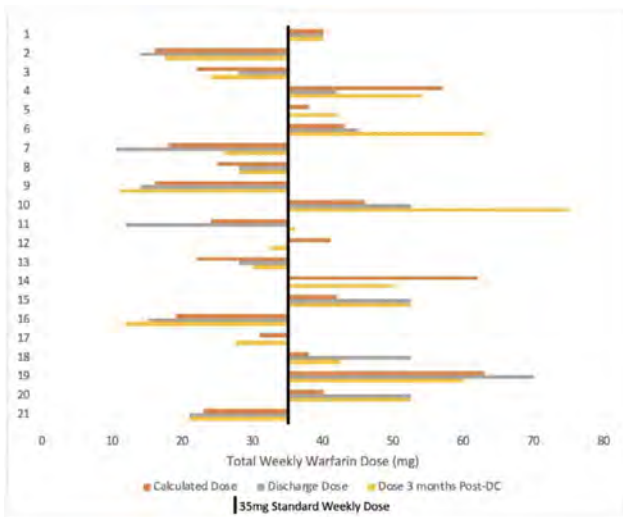
Melissa Murray, Jenny Ashton, Mohammad Al-Ani, Alex Parker, Aman Shah, Juan Vilaro, Juan Aranda, Mustafa M. Ahmed; *Cardiovascular Medicine, University of Florida, Gainesville, Florida, United States*

Background: Currently the only indicated anticoagulant for prevention of thrombotic complications in left ventricular assist devices (LVADs) is warfarin, a vitamin K antagonist. Warfarin dosing can be challenging to the clinician due to the influence of multiple inpatient variables as well as exogenous variables. Examples include diet, drug interactions, patient volume status and genetics. Multiple enzymes have been identified that influence warfarin metabolism including CYP2C9, VKORC1 and CYP4F2. Standard starting doses of warfarin in the absence of pharmacogenomic data are typically 2.5 to 5 mg daily (17.5 to 35 mg weekly). There are validated tools that can be used to calculate a patient's potential warfarin requirement using genetic testing, however it is unknown if these tools would be useful in the dynamic LVAD patient, especially in the early post-implant period.

Methods: This was a retrospective descriptive review of 21 LVAD recipients who received pharmacogenomic testing prior to or at the time of LVAD implantation who had not previously been on warfarin. The pharmacogenomic panel was a blood draw that included CYP2C9, VKORC1 and CYP4F2 variant information. Predicted warfarin doses were estimated using the International Warfarin Pharmacogenetics Consortium (IWPC) dosing calculator.

Results: Among the 21 patients, the calculated weekly warfarin dosages ranged from 16 mg to 63 mg. Actual total weekly dosages at the time of discharge ranged from 10.5 mg to 70 mg and 11 mg to 75 mg at three months post-discharge. The calculated dosages had a mean error rate of 21.6% $\pm$ 13.9% at time of discharge and 22.6% $\pm$ 17.3% at three months post-discharge with a wide range of deviation from the standard 35mg weekly dose [Fig].

Conclusion: The use of pharmacogenomic testing in LVAD recipients can be considered as a potentially useful tool in more accurately determining a patient's dosing requirements, particularly in patients who require significantly more or less than the standard 35 mg weekly dosing. Due to the limited nature of this study, it remains unknown if utilization of this testing would assist in hastening time to therapeutic INR in the post-implant period which warrants future larger studies.



P22

Successful long-term percutaneous transvalvular mechanical circulatory support without anticoagulation as a bridge to heart transplant: a case report

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Background: Traditionally the use of Impella, a percutaneous transvalvular mechanical circulatory support device, requires heparin-in-dextrose purge therapy to prevent catheter thrombosis. However, a new alternative to heparin named bicarbonate-based purge solution (BBPS) was recently approved by the Food and Drug Administration in April 2022 for when heparin is contraindicated (i.e. intracranial hemorrhage, GI bleed). Compared to heparin, BBPS has significantly lower rates of bleeding without a statistically significant increase in risk of catheter thrombosis. However, there are only a handful of cases discussing its long-term viability. The objective of this case is to discuss the longest-known course of BBPS use with an Impella device and contribute to the growing base of evidence for the viability of BBPS as an alternative to heparin.

Methods: A 62-year-old male with a history of heart failure with reduced ejection fraction (HFrEF 15-20%) and current listing for heart transplant presented with shortness of breath after missing a dose of diuretics. Initial right heart catheterization (RHC) revealed severely decreased cardiac index and cardiac output (Table 1). An intra-aortic balloon pump (IABP) was placed at this time, then surgically replaced by an Impella 5.5 three days later to have lower risk with patient ambulation. IV heparin and heparin purge solution were then started in accordance with manufacturer recommendations. On Impella post-op day 5 the patient developed hematochezia. IV heparin therapy was halted, and the purge solution was changed to sodium bicarbonate 25 mEq in D5W with no change in the purge pressure. Ultimately the bleed lasted 22 days, and the patient required 19 units of packed red blood cells before it stopped. During this time, the Impella 5.5 never sounded any alarms, purge flow never changed, and no thrombosis was observed. After the bleeding stopped, the patient successfully received an orthotopic heart transplant 41 days post-Impella placement.

Results: Following transplant, the patient was placed on an immunosuppressant and prophylactic antibiotic regimen. Serial RHC's with endomyocardial biopsies were performed showing normal filling pressures and cardiac output while pathology showed no signs of rejection. Serial echocardiograms yielded a normal EF with no signs of dysfunction. The patient is doing well to this day.

Conclusions: BBPS is a recently approved alternative to anticoagulation use for the Impella, and several case reports suggest BBPS is a viable alternative. This case report presents the longest known course of BBPS therapy and suggests that it is reliable in preventing catheter thrombosis long-term. Based on the growing evidence, more research into the long term-use of BBPS should be performed.



Figure 1. CXR upon admission. CXR demonstrating pulmonary edema.



Figure 2. EKG upon admission. EKG demonstrating a ventricularly paced rhythm.

Table 1. RHC measurements before and after transplant.

	Prior to transplant	POD 6	POD 18	POD 29	POD 43	POD 64
Mean RA Pressure (mmHg)	6	9	5	5	6	5
Mean PCWP (mmHg)	19	9	7	7	11	10
RV Pressures (mmHg)	53/0/8	35/2/7	36/0/4	29/0/3	35/-2/5	29/0/3
PA Pressures (mmHg)	54/20/32	35/7/20	31/11/20	27/11/18	35/13/22	31/9/21
CI (L/min/m ²)	1.8	2.79	3.31	3.25	3.57	3.27
CO (L/min)	3.24	4.94	5.79	5.69	6.24	5.85

RA= Right atrium, PCWP= pulmonary capillary wedge pressure, RV= right ventricle, PA= pulmonary artery, CI= cardiac index, CO= cardiac output

P23

A Novel Machine Learning Model for Predicting Risk of Requiring a Ventricular Assist Device Between Waitlist and Heart Transplant

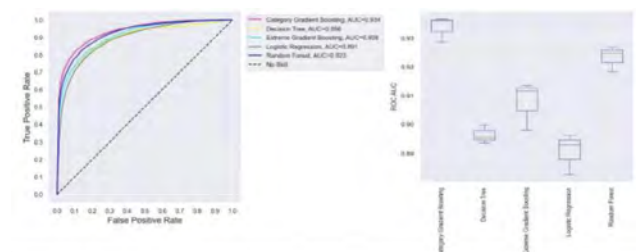
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Background: Machine Learning (ML) is an established technique for modeling associations in data and shows promise for creating predictive tools in medicine. Accurate prediction of patients requiring a Ventricular Assist Device (VAD) while on the waitlist, and the associated variables related to those predictions, could greatly assist clinicians in their decision making process surrounding patients requiring heart transplant.

Method: STREAMLINE is an automated ML tool which can apply multiple ML algorithms (Random Forest, Logistic Regression, Decision Tree, Category Gradient Boosting, and Extreme Gradient Boosting) to suitable datasets. These algorithms assess complex relationships in datasets and create a model using "training" data, then use a "testing" dataset to assess accuracy of the model. Pre-transplant recipient data from the UNOS Database for heart transplant patients that did not have a VAD at listing between July 1 2003 and June 30 2023 were cleaned and entered into the ML tool. Both a training and testing dataset were used and three iterations of each model were created in order to best validate each model.

Results: 32,729 patients were included who had received a heart transplant over the twenty year period specified but did not have a VAD at listing; this dataset included over 2,000,000 unique datapoints to be utilized in modeling. Primary endpoint was whether a VAD was implanted or not. All models had a high Area Under the Curve (AUC), or ability to accurately predict VAD implant, between 0.891 and 0.934; Category Gradient Boosting had the highest at 0.934. Feature importance evaluation revealed that increased days on the waitlist, especially increased days in higher waitlist status, recipient medical condition at listing, prior cardiac surgery, higher patient BMI, diagnosis code of idiopathic dilated cardiomyopathy, prior transplant of any organ, inotropic support, ventilator requirement at listing, and cigarette use were among the most important features in the models predicting requirement of VAD prior to transplant.

Conclusion: Our models' predictive ability are well above industry standards (AUC 0.6 to 0.7) for risk assessment, and above comparable models such as the STS Risk Calculator which has an AUC of 0.791 for Surgical Aortic Valve Replacement. These ML-based prediction models allow for increased understanding of patients who may require a VAD on the waitlist, including the ability to assess when they may require VAD after listing. The complex ML algorithms also allow us to understand some of the most common traits that influence the requirement of a VAD before to transplant.



P24

Heartmate 3 Left Ventricular Assist Device Bend Relief Disconnection Causing Laceration of the Outflow Graft

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Background: As technology in mechanical circulatory support continues to advance, so does the utilization of durable left ventricular assist devices (LVADs) as destination therapy (DT) for patients with end-stage heart failure. While the safety profile of newer devices has significantly improved, mechanical device malfunctions remain an area of concern. We present a case of mechanical device malfunction in a HeartMate 3™ (HM3) left ventricular assist device (Abbott Cardiovascular, Inc. Minneapolis, MN, USA) with bend relief disconnection causing laceration of the outflow graft.

Case Description: Our patient is a 34 year-old male with a past medical history of chronic ACC/AHA Stage D HFpEF (LVEF 20%) secondary to nonischemic cardiomyopathy status post HM3 implantation as DT complicated by recurrent driveline infections who presented in hemorrhagic shock and was subsequently found to have disconnection of the HM3 bend relief mechanism with resultant laceration of the outflow graft requiring emergent thoracotomy and repair of the outflow graft. He developed chronic driveline infections, the last tracking into his mediastinum. An anterolateral thoracotomy was performed for washout, and the HM3 device was intact and in good working order at that time. Five months later he experienced a loud “popping” sound in his chest while lifting a heavy object. Over the following week he experienced increasing fatigued and increasing sanguineous output from his previous thoracotomy incision. He was admitted and a CT of the chest was obtained (Figure 1). Shortly after the CT scan the patient experienced sudden massive decompression of the left chest hematoma from the thoracotomy incision with exsanguinating hemorrhage and an abrupt drop in LVAD flows to 0.2L/min. He was rushed to the OR where an emergent anterolateral thoracotomy was performed. Significant hemorrhage was noted coming from the HM3 outflow graft. The LVAD flow was reduced and we discovered that the bend relief had detached from the screw ring and the titanium ring on the bend relief had lacerated approximately 25% of the circumference of the graft. The graft was repaired with interrupted and running 4-0 Prolene suture reinforced with pledgets (Figure 2). The ring was removed by transecting the ring in two locations using a diamond rotary saw. The HM3 was brought back to full flow and no additional hemorrhage was appreciated. A durable wound vac was placed, and the patient was transferred to the cardiovascular intensive care unit. He underwent chest closure on postoperative day (POD) 7, was discharged home on POD 12, and has since made a full recovery.

Conclusion: Mechanical device malfunction is an established concern with LVADs. While there have been reported cases in the Heartmate 2, this is the first reported case of a HM3 bend relief disconnection. In this particular case, the disconnection resulted in laceration of the outflow graft with near disastrous consequences.

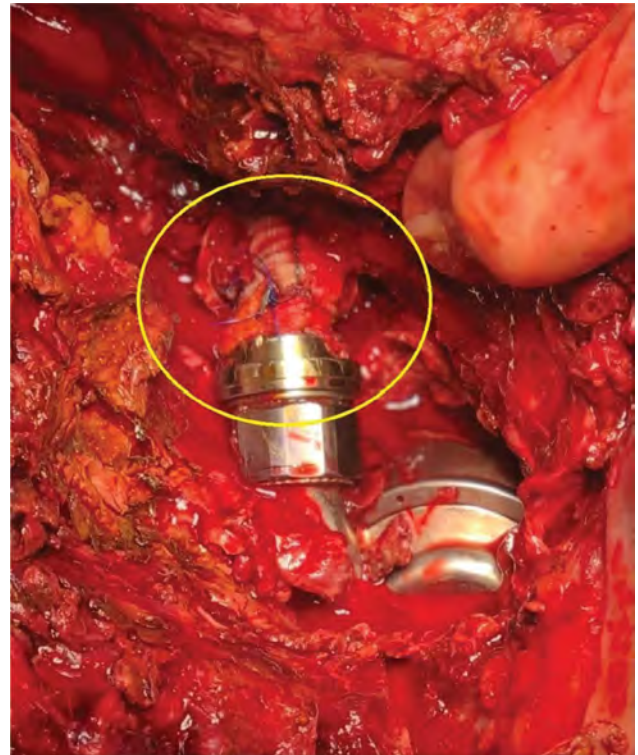


Figure 2. The Heartmate 3 device following removal of the bend relief exposing the underlying repair of the outflow graft.

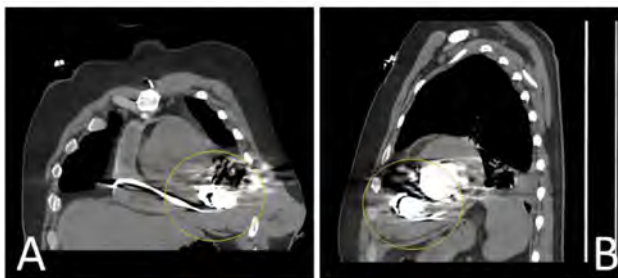


Figure 1. Computer Tomography (CT) scan of the chest showing a large fluid collection along the cardiac apex with possible extension into the left upper anterolateral abdomen, and disconnection of the HM3 bend relief in both the axial (A) and sagittal (B) views.

P25

A Bridge to Renal Transplantation using Cardiac Contractility Modulation
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Background: Cardiac contractility modulation (CCM; Impulse Dynamics) utilizes a pacemaker-like device that delivers non-conducting electrical impulses to the right ventricle to augment intrinsic cardiac contractility. While these devices are FDA-approved for NYHA Class III-IV heart failure and LVEF 25-45%, their use as a bridge for non-cardiac organ transplantation has not been established. Here, we describe the first case using CCM devices to augment cardiac function for a patient undergoing renal transplantation.

Case: A 58-year-old female with a history of pulmonary and cardiac sarcoidosis status-post S-ICD placement, end-stage renal disease due to polycystic kidney disease receiving hemodialysis was undergoing consideration for living donor renal transplantation. She developed worsening cardiac function with a reduced LVEF of 34% and diffuse dyskinesia prompting consideration of a dual organ transplant versus other advanced therapies.

Discussion: Over a year, appropriate GDMT was uptitrated with improvement in her LVEF to 42%. Despite medication compliance, she continued to experience dyspnea with minimal exertion severely limiting her activities. Given her poor performance status, her renal transplant candidacy was uncertain and with her improved EF she did not qualify for cardiac transplant. After evaluation by Electrophysiology, the patient was approved for CCM device therapy to augment her cardiac function in preparation for a renal transplant. Within just one week of placement, she noted significant improvement in her functional status - ambulating independently and completing activities of daily living without marked limitation. She did have some complications with CCM conduction due to device malfunction that were managed in the clinic. She was ultimately able to undergo renal transplantation within six months of device placement and tolerated the operation well.

Conclusion: CCM devices can serve as adjunct tools to improve functional performance in patients with heart failure who may be undergoing consideration non-cardiac organ transplantation.

P26

Time For A Paradigm Shift: Periprocedural Left Ventricular Unloading with Impella 5.5 via Brachiocephalic Artery for Low-EF, High-Risk Patients

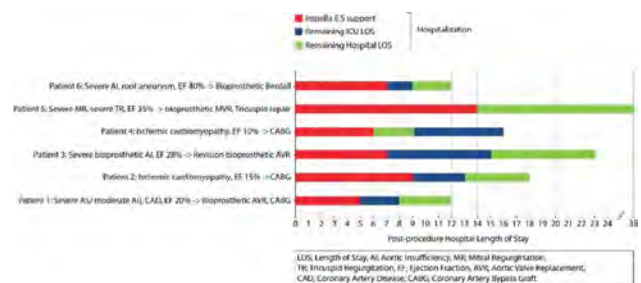
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Background: The Society of Thoracic Surgeons Adult Cardiac Surgery database indicates that 10-15% of patients undergoing cardiac surgery have significantly impaired left ventricular ejection fraction (LVEF). Low EF is an independent risk factor for post-cardiotomy shock (PCS) requiring high doses of inotropes/ vasopressors or salvage intra-aortic balloon pump (IABP) or veno-arterial extracorporeal membrane oxygenation (VA ECMO) support. We sought to evaluate potential benefits of a preemptive periprocedural LV unloading strategy with a temporary transvalvular microaxial-flow LV assist device (Impella 5.5, Abiomed) implanted via the brachiocephalic artery.

Methods: Patients with coronary artery disease and EF<20% without improvement despite low dose Epinephrine and severe aortic valve or mitral valve insufficiency with EF<25% were included. In all patients, a 8 or 10mm graft was sewn to the brachiocephalic artery using a partial clamp and tunneled to the right supraclavicular region. The guide wire was inserted into the aortic root under transesophageal echocardiography (TEE) guidance before initiation of cardiopulmonary bypass (CPB). All planned valvular and coronary procedures were performed on CPB. Prior to reperfusion, wire was guided into the LV under direct vision. Following removal of the cross-clamp, Impella 5.5 was inserted into the LV under TEE guidance. Descriptive statistics were applied.

Results: A total of 6 patients (median age 61.5 years; interquartile range [IQR] 51-68, 100% male, median EF 24%; IQR 15-34) were identified undergoing periprocedural Impella support in valvular operations (n=3), coronary artery revascularizations (n=2) or a combination thereof (n=1). All patients were weaned from CPB to Impella without need for additional mechanical circulatory support with low to moderate doses of inotropes and vasopressors, vasoactive inotropic score 12.7 (IQR 9.7-28.1). Median duration of support was 7 days (IQR 6-9). All devices were removed at bedside with no bleeding or thromboembolic complications. Median ICU and hospital length of stay was 11 days (IQR, 9-15) and 17 days (IQR, 12-23), respectively. 30-day and survival over median follow-up of 7.5 months (IQR 6-14) was 100%, respectively.

Conclusion: This proof-of-concept study may represent a paradigm shift in periprocedural management of low-EF, high-risk cardiac surgery. Rational for periprocedural Impella support include: 1) sparing of inotropic/ vasoconstrictive agents, 2) maintenance of end-organ perfusion by augmenting cardiac output during post-cardiotomy conditions, and, 3) facilitating LV recovery by decreasing of LV wall tension and myocardial oxygen consumption. Preemptive periprocedural LV unloading via Impella support may provide improved short term outcomes over inotropic/ vasopressor support, or conventional mechanical support with IABP or VA ECMO. Further investigations in patient selection and long term outcomes are warranted.



P27

Impact of Concomitant Tricuspid Valve Repair on Change in Functional Classification following Left Ventricular Assist Device Implantation at a Destination Therapy Center

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Background: Left ventricular assist device (LVAD) implantation is associated with improved functional classification. Concomitant tricuspid valve repair (TVr) may be performed to address tricuspid regurgitation and reduce risk of right ventricular (RV) failure. The impact of TVr on change in New York Heart Association (NYHA) class from baseline has not been investigated. We undertook this study in patients undergoing LVAD implantation at a destination therapy (DT) center.

Methods: We conducted a retrospective review of all LVAD implantations performed at a single, DT center. Outcomes including NYHA class were reviewed at baseline, 6, 12 and 24 months postoperatively and analyzed using Chi-square and Fisher's exact tests.

Results: From 2017-2023, 154 LVAD implantations were performed. Forty-five (29.2%) were performed with concomitant TVr and 109 (70.8%) without TVr. Prior to implantation, 122 (79.2%) patients were NYHA class IV and 32 (20.8%) were class IIIb. RV failure requiring right ventricular assist device (RVAD) and follow-up NYHA composition was similar between patients who received TVr and those who did not (Figure 1). NYHA class 1-2 composition for TVr vs non-TVr was 64.1% vs 76.2% at 6 months, 73.5% vs 78.7% at 12 months and 86.4% vs 79.0% at 24 months.

Conclusion: Concomitant TVr does not appear to have an impact on NYHA class or RV failure following DT-LVAD implantation.

	TV Repair N=45	No TV Repair N=109	p-value
Preop NYHA Class			0.8003
3	10 (22.2%)	22 (20.4%)	
4	35 (77.8%)	87 (79.6%)	
NYHA Class 6 months postop, N=123			0.2435
1	10 (25.6%)	27 (31.0%)	
2	15 (38.5%)	38 (45.2%)	
3	12 (30.8%)	17 (20.2%)	
4	2 (5.1%)	3 (3.6%)	
NYHA Class 12 months postop, N=95			1.0000
1	13 (38.2%)	21 (32.8%)	
2	12 (35.3%)	28 (45.9%)	
3	7 (20.6%)	12 (19.7%)	
4	2 (5.9%)	1 (1.6%)	
NYHA Class 24 months postop, N=63			0.3315
1	11 (50.0%)	17 (39.0%)	
2	8 (36.4%)	16 (39.0%)	
3	3 (13.6%)	8 (19.5%)	
4	0 (0%)	1 (2.4%)	
RV failure requiring RVAD	13 (28.9%)	19 (17.4%)	0.1110
Early	9 (20.0%)	8 (7.34%)	0.1288
Late	5 (11.1%)	13 (11.9%)	

Table 1. Pre- and postoperative functional classification for destination therapy: left ventricular assist device implantation with and without concomitant tricuspid valve repair.

P28

Beyond Antibiotics: Long-Term Outcomes After Surgical Intervention for Complicated Driveline Infections

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Background: Driveline Infections (DLIs) are one of the leading complications after Left Ventricular Assist Device (LVAD) implant and can substantially affect quality of life, morbidity and mortality. Ultimately the best treatment is prevention, but once established, infections can become resistant to antibiotics. In these cases, surgical intervention such as debridement, rerouting the driveline exit site and even pump exchange may be required. We sought to examine long-term outcomes for patients requiring surgical treatment for DLIs.

Methods: A retrospective analysis of all adult LVAD patients who had a DLI requiring surgical intervention at a single institution over the past ten years (10/2013–10/2023). Primary outcomes were survival and freedom from a pump exchange.

Results: Out of 212 total LVAD patients, 37 patients developed complicated DLIs requiring surgical intervention. Notably, 40.5% (n=15) of these patients either required a pump exchange or died after a mean of 448 days (SD = 379.7) post-surgery. Device types included: HeartWare 51% (n=19), HeartMate II 30% (n=11) and HeartMate 3 19% (n=7). Other baseline characteristics were similar between those who died or had a pump exchange and those who survived without a pump exchange, except for over-representation of males, Figure 1. Staphylococcus aureus was the most common (56.8%, n=21) infectious organism that required surgery to treat, Figure 1. The most common surgical intervention was Driveline Debridement, Washout and Wound Vac Placement (n=26, 70.3%), Figure 1. While 56.8% (n=21) of patients required multiple surgeries to treat the same infection, there was no statistically significant difference in composite outcomes when comparing surgical intervention type or need for multiple surgeries, Figure 1. Most patients developed their first complicated DLI around two years post-implant (mean = 794.54 days, median = 607 days), Figure 2. Freedom from death or LVAD exchange after surgical intervention for DLI was 48.6% (n=18) at one year and 35.1% (n=13) at two years, Figure 3.

Conclusion: Patient who develop complicated DLIs have a high risk of subsequent pump exchange or mortality after surgery. Therefore, prevention of DLIs is paramount to limit antibiotic resistance and adverse outcomes for LVAD patients. These results highlight the importance of the nurse's role in prevention of DLIs once the patient is discharged home. VAD Nurse Coordinators are uniquely situated to implement and reinforce best practice guidelines on wound care, prevention and early identification of infection, as well as patient education strategies. Rather than focusing on patient and caregiver education only at the time of discharge, ongoing assessments should be made throughout the duration of mechanical circulatory support to ensure patients are continuing to follow best practice guidelines on driveline exit site care and infection prevention.

Figure 1: Outcome Associations

Characteristics	Death/Pump Exchange (N=15)	No Death or Pump Exchange (N=22)	P
Baseline Demographics			
Male	14 (93.3%)	13 (59.1%)	0.03
Age (mean)	52.7	59.7	0.17
Race			0.15
Asian	2 (14.3%)	1 (27.3%)	
Black/African American	2 (14.3%)	8 (36.4%)	
Native Hawaiian/Other Pacific Islander	0 (0.0%)	2 (9.1%)	
Other	2 (14.3%)	5 (22.7%)	
White	9 (64.3%)	6 (27.3%)	
Non-Hispanic/Latino	13 (86.7%)	19 (86.4%)	1
INTERMACS Class			0.57
1- Critical cardiogenic shock	1 (6.7%)	4 (18.2%)	
2- Progressive decline	4 (26.7%)	5 (22.7%)	
3- Inotropic dependence	7 (46.7%)	6 (27.3%)	
4- Resting symptoms	3 (20%)	7 (31.8%)	
Infectious Organism			0.623
Staphylococcus aureus	6 (40.0%)	12 (54.5%)	
Corynebacterium amycolatum	0 (0.0%)	1 (4.5%)	
Staphylococcus lugdunensis	0 (0.0%)	1 (4.5%)	
Pseudomonas aeruginosa	3 (20.0%)	2 (9.1%)	
Stenotrophomonas maltophilia	1 (6.7%)	0 (0.0%)	
Proteus mirabilis	0 (0.0%)	1 (4.5%)	
Streptococcus agalactiae Group B	0 (0.0%)	1 (4.5%)	
Streptococcus pyogenes	1 (6.7%)	0 (0.0%)	
Unknown	1 (6.7%)	1 (4.5%)	
Multiple Organisms	3 (20.0%)	3 (13.6%)	
Surgical Intervention Type			0.673
Driveline Debridement & Washout	2 (13.3%)	2 (9.1%)	
Driveline Debridement, Washout, & Wound Vac Placement	10 (66.7%)	16 (72.7%)	
Pump Exchange	3 (20%)	2 (9.1%)	
Bedside Debridement & Wound Vac Placement	0 (0%)	1 (4.5%)	
Exploration	0 (0%)	1 (4.5%)	
Required Repeat Surgeries to Treat Ongoing DLI	7 (46.7%)	14 (63.6%)	0.336

Figure 2: Time from VAD Implantation to Complicated Driveline Infection

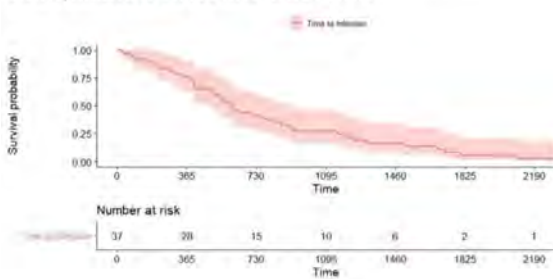
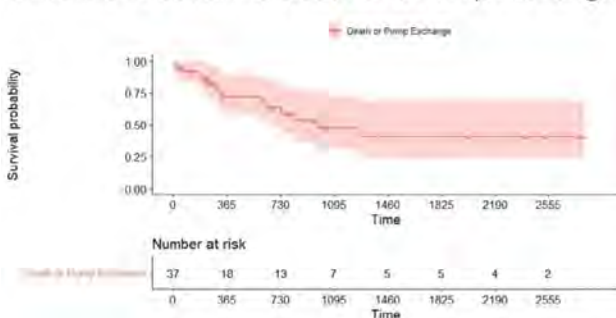


Figure 3: Survival from Surgery for Complicated Driveline Infection To Death or a Pump Exchange



P29

Outcomes of Durable Left Ventricular Assist Device Implants in the Contemporary Era: Is there a Role for Concomitant Surgery?

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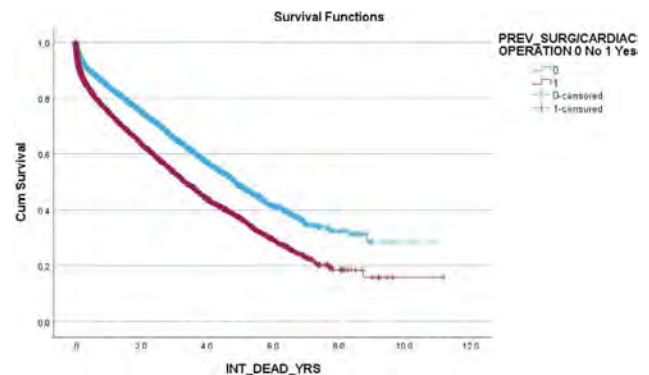
Background: Due to changes in the UNOS cardiac transplant allocation system and decreased availability of organs, the number of patients receiving durable Left Ventricular Assist Device [LVAD], and undergoing concomitant procedures has increased considerably. We examined the outcomes of these procedures performed in the last decade.

Methods: Between January 2013 and June 2023, 22474 LVAD implants were performed. Data was obtained from the INTERMACS database, analyzed using the SPSS 29.0 Statistical Package, and reported using means and standard deviations, or medians and inter-quartile ranges. Survival data and univariate predictors thereof were analyzed by the Kaplan Method using the log-rank test. Variables with $p < 0.1$ were entered into Multivariable Cox proportional hazards model to identify predictors of long-term survival, and reported as hazard ratios [HR, confidence intervals]. $P < 0.05$ denoted statistical significance

Results: In the cohort of 22474 patients, 675 patients [2.4%] were on ECMO preoperatively. Device implanted was LVAD [20782 patients, 92.5%], RVAD [31 patients, 0.1%], Bi-VADs [1198 patients, 5.3%], TAH [463 patients, 2.1%]. Concomitant surgery was performed in 9495 patients [42.2%]. Complications included renal replacement therapy ($n=684$, 3.0%), RVAD implantation ($n=116$, 0.5%), and reoperation for bleeding/tamponade/pericardial effusions ($n=1982$, 8.8%).

6606 patients [29.4%] underwent cardiac transplant, and 605 patients [2.7%] recovered. Actuarial Survival in the entire cohort was $95 \pm 0.2\%$ at 30-day, $44 \pm 0.7\%$ at 5-years, and $23 \pm 2.3\%$ at 10-years. 7766 patients [34.6%] had previous cardiac surgery, survival in this group was $37 \pm 1.1\%$ at 5-years, compared to $48.6 \pm 1\%$ at 5-years [$P < 0.001$] in the 14708 [65.4%] patients that had not had any previous surgery. 726 had ECMO explanted during LVAD implant; in this group, survival was $85 \pm 1.4\%$ at 30-days, and $50 \pm 4.7\%$ at 5-years, compared to $95 \pm 0.1\%$ at 30-days, and $44.1 \pm 0.7\%$ at 5 yrs in the no preoperative ECMO cohort; $p < 0.001$. In the Cox model, predictors of lower survival included previous cardiac surgery [HR 1.57 (1.48-1.66), $p < 0.001$] and concomitant cardiac surgery [HR 1.22 (1.15-1.3), $p < 0.001$]. Interestingly, ECMO prior to LVAD did not adversely impact survival [HR 1.04 (0.87-1.25), $p = 0.7$], nor did a high TPG [HR 1.01 (0.94-1.1), $p = 0.82$]

Conclusion: Prior cardiac surgery and concomitant cardiac surgery, but not preoperative ECMO, adversely impacted long-term survival following durable LVAD implantation



P30

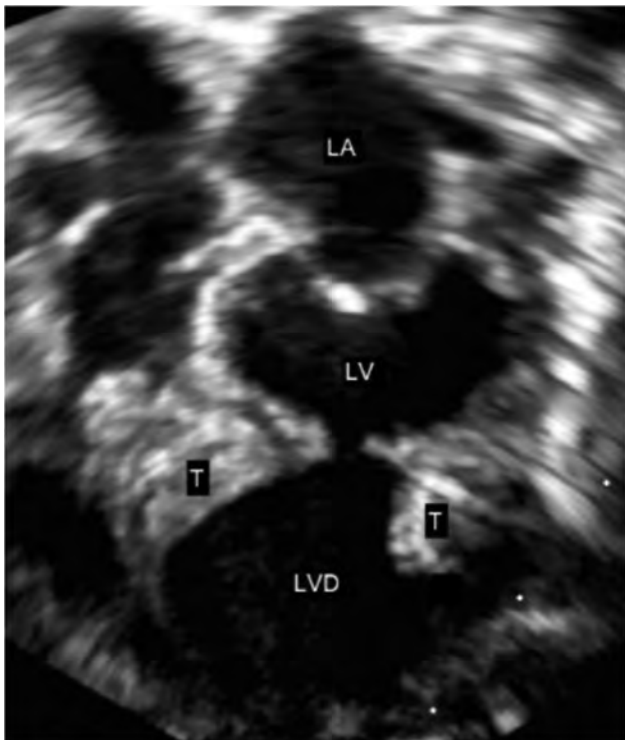
Left Ventricular Assist Device (VAD) and Orthotopic Heart Transplantation in a 2.7kg Neonate with Large Left Ventricular Diverticulum.

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Background: Left ventricular diverticulum is a rare condition with very little data on premature infants with large diverticula, particularly those requiring VAD as a bridge to transplant or surgical palliation.

Case Report: Fetal echocardiogram (echo) and post-natal echo confirmed a large communicating apical left ventricular (LV) diverticulum, LV thrombus, decreased LV systolic function, and narrowed LV outflow tract (Figure 1). He was born at 34 weeks gestation and due to a birth weight of 2.3 kg, he was not an initial VAD or transplant candidate. At 2.77 kg and 42 DOL, he underwent PediMag VAD placement through the apical diverticulum with Berlin EXCOR cannulas. An incision was made in the LV diverticulum with thrombectomy and resection of the diverticular ridge to provide an unobstructed inflow. Bivalirudin was started for anticoagulation with PTT goals in the range of 60-70 seconds. VAD flows maintained a cardiac index of around 3-3.5 L/min/m². He was listed UNOS status 1A on DOL 68- and 26-days post-VAD. His VAD course was complicated by frequent low flow alarms due to cannula position, new bilateral occipital intraparenchymal hemorrhage requiring right ventriculostomy and ventriculoperitoneal shunt, and seizures. He underwent successful orthotopic heart transplantation on DOL 229, following 187 days on VAD. Explant pathology showed biventricular cardiac hypertrophy, severe RV dilatation, diffuse severe LV endocardial fibroelastosis, patchy mild RV endocardial fibroelastosis, and interstitial fibrosis. He was discharged home 58 days after transplant.

Summary: This small premature infant with a large diverticulum underwent successful VAD placement as a bridge to transplant.



Postnatal transthoracic echocardiogram. Apical window showing left atrium (LA), left ventricle (LV), and left ventricular diverticulum (LVD) with two thrombi (T).

P31

A Straightforward, Cost-Effective, Pulse Duplicator for ECMO and CPB Cannulation and Simulation

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Background: Peripheral extracorporeal membrane oxygenation (ECMO) cannulation is well amenable to simulation, however commercial systems are either anatomically accurate vascular phantoms with air-prone gravity reservoirs or high fidelity extracorporeal simulators requiring significant financial and trainer investment. We sought to create a simple and affordable pulse duplicator to support ECMO insertion simulation for clinicians.

Methods: The guiding design objectives of the pulse duplicator were to be: 1) compact, modular, portable, and standalone for transport; 2) rapid and easily set up; 3) low (<1 L) blood analogue volume requirement; 4) quick priming and fast deairing; 5) selectable pulsatility for elective or salvage veno-arterial cannulation; 6) allow for initiation of circuit flow, 7) and low-cost.

Results: The 120V-based pulse duplicator consisted of a centrifugal pump (March Manufacturing, Glenview IL), two solenoid valves (Parker-Hannifin, New Britain CT), a recycle relay (Littelfuse Inc, Chicago IL) set at 60 cycles/min at 30% duty cycle, a three-switch control box, and a hardshell cardiectomy reservoir (Terumo Medical, Somerset NJ) modified with an additional outflow port. Echogenic vascular phantoms for bilateral femoral groin access were created using 3/8" and 1/2" ID peristaltic pump tubing (MasterFlex, Barrington IL) embedded in silicone (Smooth-On, Macungie PA) with 1% psyllium husk (Proctor & Gamble, Cincinnati OH). Total material costs were less than \$800, with the pulse duplicator itself under 7.5 kg and 0.025 m³. A schematic of the resultant flow path is shown in Figure 1-A. After filling the reservoir, deairing of the system was achieved in under one minute by opening both valves, starting the pump, and sequentially releasing then replacing the tubing clamp on the arterio-venous shunt of each phantom. Switching the **Pulse Valve** from steady to pulse mode generates a palpable pulse in the arterial vessels, along with pulsatile back bleeding (Figure 1-B) and potential for retrograde flow through the ECMO circuit. This system has been used successfully in over 25 interdisciplinary insertion simulations with significant positive feedback from cannulating physicians, first-assist advanced practice providers, perfusionists, and ECMO-trained nurses.

The pulse duplicator has since expanded to the operating theater for cardiopulmonary bypass (CPB) simulation. Commercial, pericardium and great vessels -intact, porcine hearts (Animal Technologies, Tyler TX) were prepared by placing tubing fittings in the inferior vena cava and descending aorta, before subsequently ligating the superior vena cava, pulmonary arteries, and arch vessels. The heart was then cannulated for CPB via the static right atrium and beating aorta with the ability to cross clamp, mimic arrest, and induce complications (Figure 2).

Summary: The pulse duplicator is a simple yet effective, affordable simulator to support ECMO and CPB cannulation education.

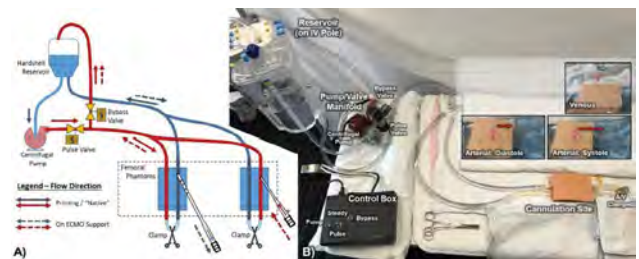


Figure 1. A) Schematic of the pulse duplicator for ECMO cannulation, and B) the setup prior to draping along with the difference in vascular back bleeding.

P32

Effect of ventricular dilation and hypertension on an edge-to-edge approach to treat FTR, an ex vivo investigation

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Tricuspid valve regurgitation (TR) is due to incomplete closure of the tricuspid valve (TV) during systole, resulting in reflux of blood from right ventricle (RV) to right atrium (RA). Functional TR (FTR), is usually induced by RV and/or RA dilatation resulting in leaflets tethering and TV annulus dilatation, preventing proper leaflet coaptation. Edge-to-edge devices aim to reduce the regurgitation gap by grasping leaflet edges. However, recent studies reported pathology recurrence. In this work we investigated the effects of ventricular dilation and pulmonary hypertension on the efficacy of an edge-to-edge approach. To do so we developed a clip prototype replicating the main functionality of an edge-to-edge device. The investigation was performed on an ex-vivo pulsatile flow setup reproducing right heart circulation on ten porcine heart samples. Tests were conducted varying ventricular dilation and pulmonary pressure in conditions of baseline and clip implantation. For each sample, we controlled ventricular dilation by mean of an adjustable band sutured around RV. Samples were tested in condition of free dilation varying pulmonary artery pressure (PAP) by increasing resistance of the pulmonary impedance simulator. Subsequently, the band was adjusted to reduce TV backflow (BF) to 50% of the initial value and tests were repeated. Pressure of RA, RV and PAP were recorded together with TV and Pulmonary valve (PV) flowrates. Echocardiographic and endoscopic imaging of samples was also acquired for morphometric and qualitative evaluations. Clip implant resulted effective over baseline condition as it induced a significant BF reduction in all tested conditions. Furthermore, no significant increase in diastolic transvalvular pressure was observed, indicating no obstruction of valve orifice. As regards morphology, clip implant induced a reduction in antero-septal TV diameter and tenting height and area, and an increase in coaptation length. The statistical analysis highlighted the ventricular pressure as the major driver of variation of the hemodynamic indexes compared to ventricular dilation. The main effects of RV dilation were a consistent yet not significant BF increase, and systolic transvalvular pressure reduction. Morphologically, RV dilation led to increased RV and TV diameters, tenting height and area. On the other hand, hypertension led to a significant increase in BF and systolic transvalvular pressure. Morphologically, pressure increase was mainly reflected by increased RV diameter. In the clinical setting, the proposed analysis might depict the consequences of hypertension and RV dilation in the acute scenario of a patient receiving an edge-to-edge device implantation. In particular, there would be a significant increase in systolic transvalvular pressure and valve BF with an increase in all the analysed morphological indexes. This may compromise the effectiveness of the device and could led to pathology recurrence and need to reoperate.

P33

Protein Disulfide Isomerase: Thrombotic Marker and Mediator Differentiating Biochemical vs. Shear-Mediated Platelet Activation

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Background: Implantable cardiovascular therapeutic devices, e.g. ventricular assist devices, heart valves, and stents, are increasingly utilized as therapy for a wide range of cardiovascular diseases. While effective these devices, impart supraphysiologic shear stress to blood transiting the device leading to platelet activation. Shear-mediated platelet activation (SMPA) is a well-recognized driver of device-related coagulopathy, however the mechanotransductive mechanisms involved remain incompletely defined. Protein disulfide isomerase (PDI) is an intracellular enzyme involved in the formation and breakage of disulfide bonds that, once released or expressed, plays a key role in thrombosis. Here, we aim to define the level of expression of PDI in platelet activation. We hypothesize that PDI expression on platelets will be distinct between shear-mediated and biochemical-mediated platelet activation pathways. We investigated PDI expression on human platelets following calcium ionophore or supraphysiologic shear (70 dyne/cm²; 10 min) exposure.

Methods: Human gel-filtered platelets (100,000/ μ L) were obtained from ACD-A anticoagulated whole blood. Platelets were re-calcified to reverse citrate (3mM CaCl₂) and then incubated at 37 C with calcium ionophore (10uM) or exposed to uniform shear stress in a modified cone and plate viscometer (HSD, 70 dyne/cm²; 10 min). Platelets were collected and dual stained with fluorescent-tagged antibodies (anti-CD41-APC and anti-PDI-FITC) via room temperature incubation for 1 hour. Samples were fixed with 2% paraformaldehyde for 30 min and diluted in phosphate buffered saline for flow cytometry. Flow cytometry was performed on FACScantoII (BD Biosciences) and analyzed for % positive PDI expression using FCS Express (V7 DeNovo Software). All experiments were performed in duplicate from N = 4 donors and data pooled.

Results: Compared to resting platelet control ("Rest") exposure of platelets to pathologic shear stress led to a non-significant mild increase in PDI expression (average 4% increase). Notably, calcium ionophore exposure led to a much greater significant increase in expression (p < 0.01; average 27% increase); similarly, calcium ionophore led to significantly higher PDI positive population compared to shear (p < 0.005; average 23% increase).

Conclusion: Platelet protein disulfide isomerase expression increases with both mechanical (shear) and biochemical (Ca ionophore) activation agonist exposure. Notably, biochemical mediation of platelet activation led to more significant alterations (increase) in PDI platelet expression as compared to SMPA. This distinction in PDI levels holds promise for development of both diagnostic and therapeutic strategies to detect and limit SMPA. Further, defining the role of PDI in biochemical and mechanical platelet activation will further advance our basic mechanistic understanding of thrombosis.

P34

It's Not the Heat, It's the Humidity: A Silver Based Antimicrobial LVAD Driveline Exit-Site Experience in a Subtropical Climate

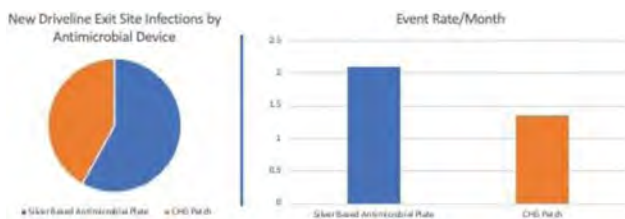
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Background: Meticulous driveline exit-site care is of critical importance to prevent infections, which are a major contributor to left ventricular assist device (LVAD) complications, and may increase post-implant morbidity and mortality. Standardized driveline exit-site care protocols and patient kits may reduce driveline infection rates. However, the impact of any individual components of these protocols and patient kits have not been assessed. We therefore sought to examine our rates of new driveline exit-site infections with a silver based antimicrobial plate versus a chlorhexidine gluconate impregnated patch (CHG).

Methods: A retrospective, single center review of all new driveline exit-site infections from 1/21-12/23 was performed. New dressing kits with silver based antimicrobial plates were sent to all LVAD patients beginning 9/22, replacing CHG patches. The incidence of new driveline exit-site infections was compared before and after this change.

Results: A total of 62 new driveline exit-site infections were documented during the study time period. Of these 26 (42%) occurred with CHG patches and 36 (58%) occurred with a silver based antimicrobial plate. There were no significant differences between groups in regard to age, gender, presence of diabetes, or BMI. The event-rate of new infections per month was higher in the silver based antimicrobial plate group (1.36 vs 2.11) [Fig].

Conclusions: In our single-center experience, a silver based antimicrobial plate was associated with an increased incidence and event rate of new driveline exit-site infections, despite changing no other components of our driveline exit-site care protocols and patient kits. Product inserts suggest moistening the silver plate prior to its application, however, in humid and subtropical climates, this may not be ideal. Further evaluation of components of driveline exit-site care protocols and patient kits is warranted.



P35

Veno-Arterial Extracorporeal Membrane Oxygenation in Pregnancy: A Case Report

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Background: Indications for veno-arterial extracorporeal membrane oxygenation (VA ECMO) in pregnancy are the same as non-pregnant patients with viable pregnancy considered beyond 24 weeks. Despite only five case reports of VA ECMO in pregnancy and low maternal and fetal survival rates, we demonstrate the ability for safe use of VA ECMO in pregnancy and review special considerations for its use due to physiological differences.

Methods: This is a single patient case report of a 23-year-old female presenting in cardiogenic shock requiring escalation of mechanical circulatory support. Written informed consent was obtained for the two patients described herein.

Case: A 23-year-old female at 29 weeks gestation was transferred to our facility for spontaneous coronary artery dissection of the distal left posterolateral artery. She had normal biventricular function and was discharged without intervention. Three days later, she was transferred back to our institution with recurrent ischemia after experiencing profound psychological distress. Emergent coronary angiography showed a stable LPL dissection and no obstructive coronary artery disease. During catheterization, she was intubated for worsening hypoxia and her hemodynamics worsened despite inotropic support and right femoral Impella CP placement. Left ventriculogram demonstrated left ventricular failure (ejection fraction = 20%) and right heart catheterization confirmed right ventricular failure. Multidisciplinary discussion determined biventricular support was necessary and she was cannulated for peripheral VA ECMO via left femoro-femoral approach. Upon arrival to the intensive care unit, fetal distress progressing to fetal bradycardia was noted on monitoring necessitating emergent bedside Cesarean section. Early reconfiguration was pursued and the right femoral Impella CP was exchanged for a right axillary Impella 5.5 on hospital day two allowing for ECMO decannulation on hospital day three. Left ventricular function recovered to 42% on hospital day four and the Impella was weaned and removed on hospital day five. She was weaned off inotropes on hospital day nine and subsequently discharged home. She is doing well at four-month follow-up with her most recent echocardiogram showing an ejection fraction of 45%. Final diagnosis was consistent with Takotsubo cardiomyopathy. The baby required intubation, but extubated on day of life 2, and discharged home at 4 weeks old.

Conclusion: VA ECMO may be considered for refractory cardiogenic shock in pregnancy despite a paucity of literature. Early multidisciplinary involvement at a tertiary center is of paramount importance. Pregnancy results in higher cardiac output, which should be considered with ECMO flows and a higher sweep is necessary to induce a respiratory alkalosis to maintain an appropriate transplacental carbon dioxide gradient for fetal gas exchange.

P36

Prolonged Mechanic Circulatory Support with Impella 5.5 used as a Bridge to Transplant in a Patient with Post-MI Ventricular Septal Defect and Cardiogenic Shock, a Case Report

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Case presentation: A 62-year old female with no known cardiac history, presents with a 7 day history of chest pain and progressive shortness of breath. On admission, her exam was remarkable for a new prominent holosystolic murmur, and pulmonary crackles.

Chest x-ray showed pulmonary edema. EKG had evidence of inferior myocardial infarct, but no ST elevations. Coronary angiogram revealed a culprit 100% thrombotic occlusion of distal right coronary artery and diffuse 50% stenosis of multiple other arteries. Echocardiogram demonstrated a ventricular septal defect (VSD) of 2.1cm with evidence of left to right shunting, moderately reduced left ventricular ejection fraction 45-50% and mildly reduced right ventricular function.

Patient was emergently hospitalized for progressing cardiogenic shock (CS) and required intubation for stabilization and placement of cardiac assist device.

Intervention and follow up: Patient underwent placement of right axillary Impella 5.5 on hospital day 1 with initial settings of P7 (3.9-4.5 L/min). Hemodynamic stability was achieved without the need for inotrope or vasopressor support and she was extubated to room air on hospital day 2. Evidence of appropriate LV afterload reduction without inducing right to left shunt was demonstrated by ability to maintain oxygenation > 92% on room air. On hospital day 10, repeat echocardiogram revealed worsening ventricular septal defect to 4cm with mitral valve impingement and she was listed for heart transplant, status 2e.

While awaiting transplant, the Impella had to be repositioned twice on hospital day 15 and 25 without any hemocompatibility complications. Support was weaned down to P4 (1.9-3.3L/min) on hospital day 25; bedside echocardiogram confirmed appropriate positioning with adequate unloading.

She underwent heart transplant on hospital day 43, discharged on day 58 and was alive/well at 3 month follow up. Serial angiography has demonstrated normal cardiac function and biopsies have not shown evidence of rejection.

Discussion and Conclusion: Post-Infarct VSD (PIVSD) is a devastating complication of MI with one month mortality of 94% if treated supportively vs 40% if surgically intervened on. Due to early post-MI friability of peri-VSD tissue, timing of surgical repair also affects mortality with an improvement of 54% to 18% when surgical repair is delayed beyond 7 days. The ideal strategy for achieving hemodynamic stability until appropriate surgical intervention can be achieved remains controversial.

Though Impella has not been approved for use in CS complicated by VSD, it has been used as a rapid bridge to transplant in several cases and a recent case series has shown improved survival outcomes with early implantation. This case represents one of the first reported uses of Impella as a sole agent for prolonged bridge-to-transplantation and highlights its potential superiority for this purpose with lack of hemocompatibility or other complications.

P37

A Method for Tuning the Pulsatile Energy Created in Continuous Flow VADs

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Purpose of Study: Many continuous flow (CF) ventricular assist devices (VADs) currently on the market or under development incorporate impeller speed modulation algorithms that can create artificial pressure pulses to disrupt the flow field and generate washout. However, the effect of different speed modulation strategies on facilitating favorable hemodynamics to reduce thromboembolic risks and GI bleeding remains unknown. Surplus hemodynamic energy (SHE), a function of pulse frequency (PF) and pulsatility index (PI), can be used to quantify the pulsatile energy added to the systemic circulation. Hence, we aim to characterize SHE created by a square waves with varying PF and PI values and tune the speed modulation to match the SHE of a healthy subject.

Methods: Using a mock circulatory loop (MCL) with a programmable in-house centrifugal VAD model, patient hemodynamics were established for healthy and heart failure (HF) conditions. The VAD model was then operated at 5 L/min to simulate full VAD support. Rotational speed modulation strategies were assessed at the full VAD support condition using a square wave. The effect of the PI and PF on SHE was analyzed, and other key hemodynamic parameters, such as atrial/ventricular/aortic pressures, mean arterial pressure (MAP), and pulse pressure (PP) were recorded.

Results: Target SHE values were achieved by modulating pulse frequency and PI. The observed SHE in a simulated HF patient undergoing full CF VAD support was nearly zero, but pulsatility effects were observed by introducing impeller speed modulation. The total cardiac output and average impeller speed were not impacted by the impeller speed modulation algorithms. As expected, increasing the PI increased SHE (Fig. 1), while increasing the PF reduced the slope of the PI vs SHE curve. At pulse frequencies of 6 and 10 pulses per minute, the VAD model created a SHE meeting or exceeding the expected values for a healthy heart at high PI values. At these conditions, the aortic valve was open for greater than 10% of the cardiac cycle for all conditions.

Summary: Restoring pulsatile energy to circulating blood in patients undergoing CF VAD therapy may help to reduce adverse events and better preserve vascular function and protect the aortic valve. Our work demonstrates a method of characterizing and tuning pulsatile energy for a VAD in an MCL. Our system was able to achieve tunable SHE values matching those seen in healthy patients.

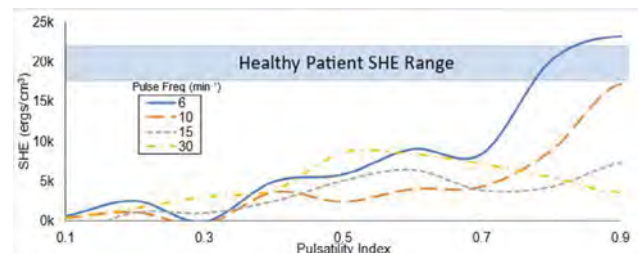


Figure 1. Graph showing the SHE generated by modulating the PI and pulse frequency of a VAD model. For each condition, the mean flow rate and average rotational speed were held constant at 5 L/min and 2200 rpm, respectively.

P38

Friday TAVRs are associated with extended hospital stay

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Background: Transcatheter aortic valve replacement (TAVR) procedures have increased over the past few years, most commonly via the transfemoral (TF) approach. At our institution, TAVRs were performed on Mondays, Wednesdays, and Fridays (old policy). The majority of TF TAVRs were discharged on postoperative day 1 or 2. However, with procedures performed on Fridays, discharges may run into issues over the weekend. Fewer staff and resources available on the weekend can extend a patient's hospital stay. As a result, in March 2022, we changed our policy and limited performing TAVRs to Mondays and Wednesdays to reduce Friday TAVRs (new policy). We aim to compare the admission in Friday versus non-Friday TAVRs and analyze the effect of our policy change.

Methods: This is a single-center retrospective study of TF TAVRs. Patients who received this procedure from January 2020 to March 2023 were included in this study. The inclusion criteria consisted of same-day TF-TAVR patients with no scheduled concomitant procedures. Exclusion criteria included non-TF TAVRs and patients who developed major complications. Patient pre-operative demographics, total in-hospital stay, and day of procedure were collected. Patient data was stratified based on receiving their TAVRs under the old policy (Group 1) versus the new policy (Group 2). Group 1 was sub-grouped into two groups: Group 1-MW for procedures performed on Mondays and Wednesdays and Group 1-F for procedures performed on Fridays. One-way ANOVA and Kaplan-Meier analysis were used for statistical analysis. The primary outcome analyzed was the length of hospital stay.

Results: The number of patients within the total cohort, Group 1, and Group 2 were 307, 197 (64.17%), and 110 (35.83%), respectively. Group 1 sub-analysis comparing Group 1-MW (75.63%) and Group 1-F (24.37%) showed that the average hospital duration of Group 1-F was significantly longer than Group 1-MW (2.35 days vs 1.75 days, $p < 0.01$). Group 1-F was associated with a significantly increased risk of lengthy hospital stays compared to Group 1-MW (Figure 1A, $p < 0.01$). Post-policy change, Group 2 had a statistically significant shorter mean hospital duration than pre-policy change Group 1 (1.30 days vs 1.89 days, $p < 0.01$). The new policy is associated with significantly reduced risk of prolonged hospital stays than the old policy (Figure 1B, $p < 0.01$).

Conclusion: Among the scheduled same-day TF TAVR cases with no complications, Friday cases were associated with lengthier hospitalizations. The new policy to limit TAVRs on Fridays successfully reduced hospital stays. Further studies are warranted to evaluate the cost-effectiveness of this policy.

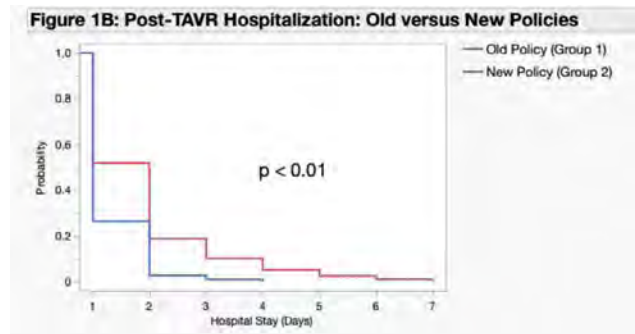


Figure 1B. Post-TAVR Hospitalization: Old versus New Policies. The new policy is associated with significantly reduced risk of prolonged hospital stays than the old policy ($p < 0.01$).

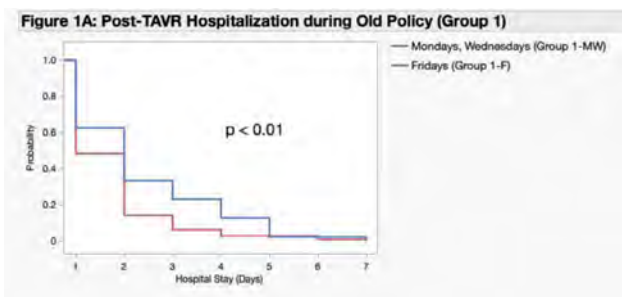


Figure 1A. Post-TAVR Hospitalization during Old Policy (Group 1). Within Group 1, patients who underwent TAVRs on Fridays (Group 1-F) have a significantly increased risk of prolonged hospital duration ($p < 0.01$).

P39

Increased VA-ECMO pump speed is associated with reduced left atrial pressure in the presence of ventricular interdependence and a Frank-Starling mechanism

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Background: Although venoarterial extracorporeal membrane oxygenation is a mainstay treatment of advanced heart failure and cardiogenic shock, it may be associated with increased left atrial pressure (LAP), left ventricular (LV) distension, thrombus formation and pulmonary oedema. However, the predictors of adverse haemodynamic effects of V-A ECMO in the presence of ventricular interdependence and a Frank-Starling mechanism are unknown.

Methods: A mock circulatory loop with separate left and right ventricles and without a Frank-Starling mechanism was utilised to assess the impact of VA-ECMO on LAP. This was then repeated in a 3D biventricular heart model (Figure 1) incorporating a Frank-Starling mechanism. In each configuration, LV contractility and ECMO pump speed were altered to assess their independent effects on LAP.

Results: Increased ECMO pump speed ($\beta = 0.012$, $p < 0.0001$) and decreased LV contractility ($\beta = -10.67$, $p < 0.0001$) were predictors of increased LAP in a separate-ventricle model without a Frank-Starling mechanism (Figure 2a). Decreased ECMO pump speed ($\beta = -0.006$, $p < 0.0001$) and decreased LV contractility ($\beta = -9.771$, $p < 0.0001$) were predictors of increased LAP in a biventricular model with an active Frank-Starling mechanism.

In the biventricular model with a Frank-Starling mechanism, ECMO pump speed modulated the MAP-LAP relationship, with LAP being minimally sensitive at high ECMO pump speeds, highly sensitive at mid-range ECMO pump speeds and both LAP and MAP stabilising at the highest ECMO pump speeds (Figure 2b).

Conclusion: The effect of V-A ECMO on LAP is attenuated in the presence of ventricular interdependence and a Frank-Starling mechanism, with higher ECMO pump speed associated with decreased LAP.

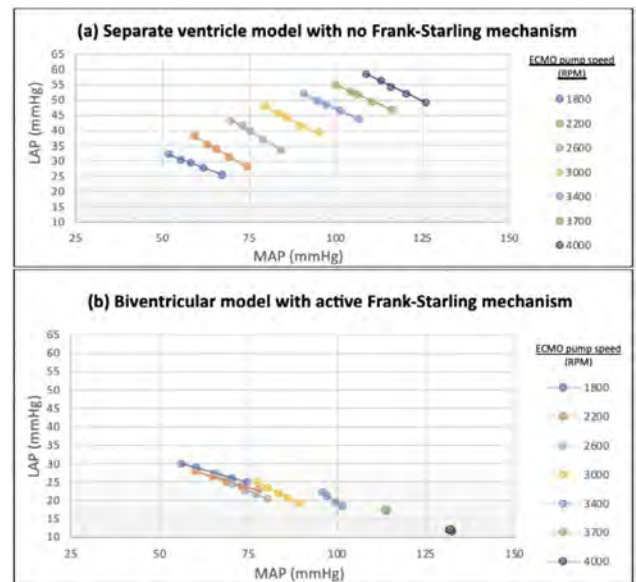


Figure 2. The leftmost point along one ECMO speed was at low contractility, and the rightmost at a high contractility. (a) The relationship between MAP and LAP for a given ECMO speed with different LV contractilities in a separate-ventricle model. (b) The relationship between MAP and LAP for a given ECMO speed with different LV contractilities in a biventricular model with a Frank-Starling mechanism. MAP = mean aortic pressure, LAP = left atrial pressure.

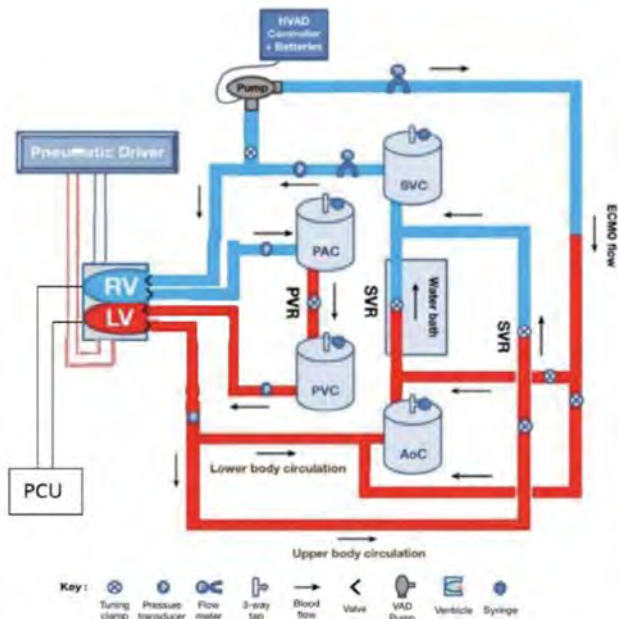


Figure 1. Biventricular heart model and MCL schematics. RV = Right ventricle, LV = left ventricle, PVC = pulmonary venous compliance, PAC = pulmonary arterial compliance, SVC = systemic venous compliance, AoC = Aortic compliance, SVR = systemic venous resistance, PVR = pulmonary vascular resistance, ECMO = extracorporeal membrane oxygenation, HVAD = HeartWare Ventricular Assist Device, PCU = pressure control unit.

P40

Feasibility Testing of the Bionet Sonar Transcutaneous Energy Transmission System for Wireless Power and Communication of a LVAD

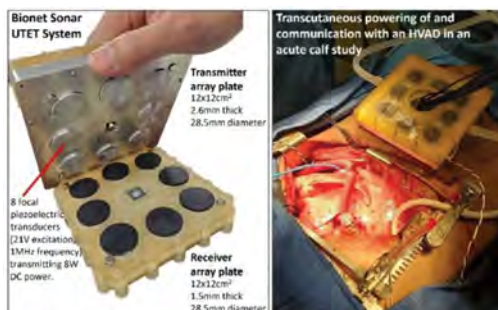
Grete Monreal¹, Steven C. Koenig⁴, Amit Sangwan³, Rafaela Guida³, Jiapeng Huang², Emrehan Demirci³, Tommaso Melodia³, Jorge H. Jimenez³, Mark S. Slaughter¹; ¹Cardiovascular and Thoracic Surgery, University of Louisville, Louisville, Kentucky, United States, ²Anesthesiology and Perioperative Medicine, University of Louisville, Louisville, Kentucky, United States, ³Bionet Sonar, Burlington, Massachusetts, United States, ⁴Bioengineering & Cardiovascular and Thoracic Surgery, University of Louisville, Louisville, Kentucky, United States

Background: Bionet Sonar (Burlington MA) is developing an innovative transcutaneous energy transmission system (TETS) using ultrasonic wide band (UsWB) technology for wireless power transmission and bidirectional real-time communication of a LVAD. The UsWB system (UTET) transmits energy (1MHz) and data (250kHz) via ultrasonic waves through tissues/bone with 10cm penetration (greater depth and reliability than radiofrequency waves) while staying below the FDA limit on ultrasound exposure (720mW/cm).

Methods: The novel UTET system consists of an energy transfer portal with internal and external smart piezo array-surfaces, implantable controller with energy storage, external controller, and external batteries. Two piezo electric array plates transfer and receive data and energy transcutaneously via UsWB from an external transmitter array plate (skin), and internal receiver array plate (subcutaneous pocket in the chest) aligned with the transmitter. The 12x12cm² array plates each contain 8 focal piezoelectric transducers (21V excitation, 1MHz frequency). The transmitter (2.6mm thick, 28.5mm diameter) and receiver (1.5mm thick, 28.5mm diameter) can transfer 8W DC power to continuously charge 2 internal batteries (14.8V 4400mAh) that alternate between powering the LVAD until 50% life left (battery-1) and recharging (battery-2) to 100% capacity. A pair of sphere transducers (250 kHz) are connected to external and implanted UsWB data communication boards. Feasibility testing of the prototype UTET system with a Medtronic HVAD was completed in static and dynamic mock flow loops over a range of pump speeds (1800, 2400, 3000 RPM) and tissue analogue thicknesses (5, 10, 15mm), and in an acute calf model.

Results: In mock loops, the UTET system successfully powered and communicated with the HVAD to deliver flows of 5L/min at 3000 RPM, and all pump speeds and flows were achieved for all tissue analogue thicknesses. In the acute animal, the UTET system wirelessly powered and communicated with the HVAD to deliver up to 4.4L/min flow at 3000 RPM, with the received (harvested) power above HVAD power requirements at 1800, 2400, and 3000 RPM. Skin temperature was 38°C and histology showed no evidence of thermal injury.

Conclusion: The prototype UTET system demonstrated feasibility by achieving function, operation, and performance metrics with no system failures, including achieving receiver (harvested) power exceeding HVAD power requirements, data communication rates of 10kB/s, and pump speed control (>95% sensitivity and specificity) for all test conditions, and normal tissue temperature. This promising platform technology and preliminary findings demonstrate potential for advancing the field toward a totally-implantable LVAD system featuring wireless power and bidirectional real-time communication with the goal of eliminating drivelines and overcoming challenges associated with wireless power and data transfer to help improve patient outcomes and quality of life.



P41

Massive Pulmonary Embolism with Venoarterial Extracorporeal Membrane Oxygenation Rescue In A Patient Recently Started On Semaglutide: A Case Report

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Body: An active 45-year-old female presented to the emergency department with acute worsening shortness of breath. Her past medical history was notable for type II diabetes mellitus and morbid obesity (BMI 53).

On presentation she was hypoxic, SpO₂ 80% on room air, with increased work of breathing. She denied fever, chills, chest or back pain, recent surgery, leg pain or swelling, or a history of deep vein thrombosis or pulmonary embolus. She endorsed being started on Semaglutide approximately six weeks prior for her diabetes management. Given her clinical picture and suspicion for a pulmonary embolism, CTA chest revealed a large saddle embolus with multiple segmental pulmonary emboli.

Due to her worsening hemodynamics, she was started on vasopressor and inotropic support to combat the worsening obstructive and cardiogenic shock. She was immediately taken to the interventional radiology suite for attempted mechanical thrombectomy. Multiple large segments of thrombus were removed. Given the burden of the pulmonary emboli, she was also given systemic Tenecteplase after the procedure. Despite this, cardiogenic shock continued to worsen. Her vasopressor and inotropic requirement continued to rise. Bedside limited transthoracic echocardiography revealed a severely dilated right ventricle with significant depression of systolic function. The shock team was consulted for mechanical circulatory support evaluation, and she was taken to the operating room for peripheral venoarterial extracorporeal membranous oxygenation (VA ECMO) via cutdown on the femoral vessels. After the initiation of VA ECMO her acid base status improved. She remained intubated and sedated on five liters per minute of VA ECMO support. On post VA ECMO day 2 she underwent a successful ECMO weaning trial and on ECMO Day 3 she was successfully decannulated in the operating room with near recovery of her right ventricular systolic function. Of note, a hypercoagulable workup returned without abnormality.

Methods Case study: Conclusion: This case represents the first reported use of ECMO support in a patient with massive PE following the initiation of Semaglutide. Recent meta-analysis of the SUSTAIN and PIONEER trials showed that while Semaglutide has a good safety profile in general, there was an 266% increase in deep vein thrombosis vs those not on Semaglutide. Our patient had a history of type II diabetes for which she was started on Semaglutide six weeks prior to this event. She was a very active individual who had been on oral contraceptives for years prior. Given no history of prior deep vein thrombosis or pulmonary embolism, personal or family history of a hypercoagulable state, we believe this event was likely precipitated by the side effect of Semaglutide. With the prevalence of type II diabetes and obesity increasing, as well as the use of this and other GLP-1 inhibitors, it is possible that clinical suspicion for massive PE and necessary shock team management of these patients be considered.

P42

Veno-Arterial Extracorporeal Membrane Oxygenation as a Bridge to Diagnosis and Treatment of Chronic Thromboembolic Pulmonary Hypertension

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Background: The use of veno-arterial extracorporeal membrane oxygenation (VA-ECMO) as a bridge to diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) and subsequent treatment with pulmonary endarterectomy (PEA) in the patient with shock and severe pulmonary hypertension has not been well-described. We report the use of VA-ECMO as a means of support to allow for the diagnosis and surgical treatment of CTEPH with excellent long-term results.

Case: A 54-year-old female with a history of hypertension was transferred to our institution with a new diagnosis of severe pulmonary hypertension. She had no known history of deep venous thrombosis or pulmonary thromboembolism. She presented alert but in distress with a blood pressure of 99/52 mmHg requiring multiple vasopressors and a pulmonary arterial (PA) pressure of 95/35 mmHg despite treatment with milrinone. Given her critical condition, we proceeded with awake femoral VA-ECMO cannulation as a bridge to diagnosis.

Bifemoral VA-ECMO was initiated. Echocardiography was significant for right ventricular dilation with severe dysfunction. Her hemodynamics improved over the next 48 hours and a bedside ventilation-perfusion scan was performed. This demonstrated filling defects consistent with pulmonary thromboembolism. Computed tomography pulmonary angiogram (CTPA) subsequently demonstrated a large right PA thrombus extending to segmental levels and thrombosis of the left PA which appeared chronic (Image 1). Percutaneous thrombolysis was attempted utilizing ultrasound-assisted catheter-directed thrombolysis. Repeat CTPA demonstrated no change in thrombus burden, consistent with chronic disease, thus the diagnosis of CTEPH was made. As the patient was unable to be safely weaned from VA-ECMO, the decision was made to proceed with PEA.

PEA was performed successfully, removing a large chronic thrombus from the main and right PA. On postoperative day (POD) 4, she was weaned from VA-ECMO and decannulated. She was extubated on POD 5 and discharged to inpatient rehabilitation on POD 20. At 6-month follow-up, she was ambulatory on room air with a 375-meter six-minute walk test.

Conclusion: VA-ECMO can be used as a bridge to diagnosis of CTEPH and for perioperative support for PEA, in the patient presenting with shock and severely elevated PA pressures.



Image 2. Surgical specimen of large chronic right pulmonary artery thrombus.

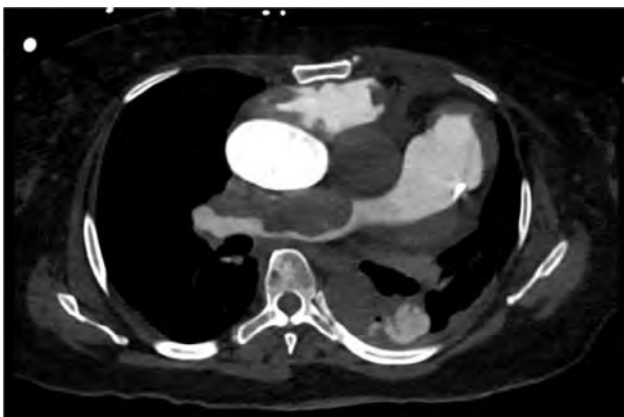


Image 1. Computed tomography pulmonary angiogram axial image demonstrating large right pulmonary artery thrombus.

P43

Successful heart transplantation after 24 hours and different weather condition using Portable Ex-situ Normothermic ECMO Technology

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Background: The quality of donor hearts is one of the key determinant of transplantation success. We present a model of self-contained portable NESHP using that resulted in successful orthotopic heart transplantation (HTx) after 24-hours with different weather condition (-40°C degree).

Methods: Ten healthy adult domestic pigs weighing 90-95 kg were utilized in this pilot study (n=5 donors and n=5 recipients). All pigs received **Principles of Laboratory Animal Care**. All hearts were procured and maintained on our NESHP system for 24 hours in different weather condition (Figure 1). In our NESHP system, coronary arteries are perfused with oxygenated blood by a centrifugal pump. All hearts underwent NESHP with cPH incorporated with the circuit. At end perfusion, hearts had low serum lactate levels (4.4 ± 1.4 mmol/L). Five hearts were arrested with normothermic blood cardioplegia and transplanted into the recipient pigs using an orthotopic technique. Haemodynamics by thermodilution method and echocardiography were utilized to assess hearts after 6 hours post-transplant.

Results: The mean ischemic time prior to NESHP was 21.2 (± 3.3) min. Mean ex-situ perfusion time was 24 h (± 80 min). The time of sinus rhythm restoration on NESHP was 2.5 (2.2) min. All isolated hearts had stable perfusion, biochemical and histological characteristics in the perfusion system. The mean venous lactate trend are with normal levels at the end of perfusion. The mean left ventricular ejection fraction after HTx was 48% (± 0.8) and normal TDI parameters Figure 2. Mean cardiac output and cardiac index after HTx was 5.1 (± 0.9) and 3.0 (± 0.2) respectively.

Conclusion: Ex-Situ Normothermic ECMO technology with Continuous Perfusate Hemofiltration allows safe preservation of myocardial function leading to successful heart transplantation after 24 h with different weather condition (-40°C degree).

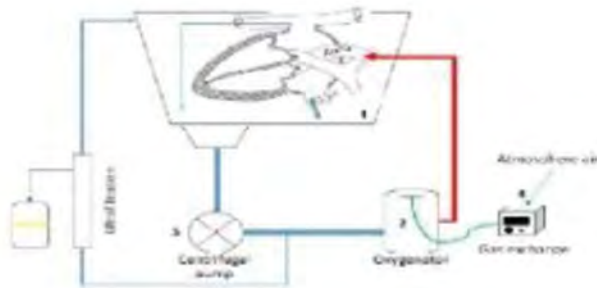


Figure 1. The scheme and picture of portable ex situ perfusion system (our development) 1-integrated box reservoir for a donor heart placement, 2- oxygenator, 3-centrifugal pump, 4- gas exchange using of atmosphere airflow and lines connecting all components.

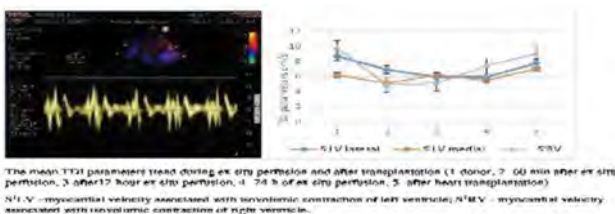


Figure 2. The mean TDI parameters trend during ex situ perfusion

P44

Coronary perfusion post Valve-in-Valve procedure a high-risk aortic root anatomy – in-vitro experimental study

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Background: Transcatheter aortic valve-in-valve replacement (ViV) has been reported as a less-invasive alternative to re-do surgery in patients with bioprosthetic valve failure. Coronary occlusion is a rare but life-threatening complication post-ViV. Meticulous pre-procedural planning is required to define the size and type of prosthesis as well as assess the risk of coronary occlusion (CO) related to a particular patient's aortic root (AR) anatomy.

This study aimed at developing an in-vitro experimental setup and protocol for predicting coronary perfusion post-ViV procedure in AR anatomies considered at risk for CO.

Methods: A female patient undergoing ViV with an associated Chimney technique on the left coronary artery (performed as a precautionary measure) was selected as a case study. The particular geometry of her AR was considered to pose a high risk of CO post-ViV. Starting from the CT image of the patient, a 3D-printed patient-specific AR model was obtained.

Subsequently, the same type of prostheses implanted in the patient were used to simulate the ViV procedure. Trifecta 19 (Abbott, St. Paul, MN, USA) was housed inside the AR model, and a TAV CoreValve Evolut 23 (Medtronic, Maastricht, NL) was implanted at five different heights with respect to the surgical prosthesis annulus. For each height, the TAV was implanted in two configurations, i.e., with commissures aligned (0°) and misaligned (60°) with respect to the surgical prosthesis commissures. The AR model was incorporated into a pulsatile flow in-vitro bench setup equipped with a coronary perfusion simulator. Each test was performed pre- and post-ViV procedure under typical rest conditions (heart rate 60 bpm, stroke volume 80 mL, mean aortic pressure 100 mmHg). The coronary simulator resistance values were adjusted at baseline (pre-ViV) to obtain physiological coronary flow values. Then the resistances were kept constant, allowing for the detection of the potential influence of the ViV procedure on the coronary flow. Each testing condition was repeated three times. The data were assessed for normality and compared using a repeated measures ANOVA.

Results: The experimental design provided controllable and repeatable flow and pressure conditions. The left and right coronary mean flow did not differ significantly between pre- and post-ViV procedures in any of the tested configurations. The commissural misalignment did not induce any significant alternations in the coronary flow.

Conclusion: In this proof-of-concept in-vitro experimental study, the AR geometry considered high-risk for CO post-ViV did not provoke any relevant coronary flow alternations for the tested conditions. This study demonstrated how adopting a meticulous method can provide surgeons with support in preoperative planning and prevent unnecessary procedures that would increase the postoperative risk for the patient.

RESULTS – Coronary parameters and mean right and left coronary flow pre- and post-Valve-in-Valve procedure. No statistically significant differences were detected.

	Post Valve-in-Valve											
	Baseline				This procedure				Second procedure			
	Heart rate, bpm	Stroke volume, mL	Mean aortic pressure, mmHg	Mean left coronary flow, mL/min	Heart rate, bpm	Stroke volume, mL	Mean aortic pressure, mmHg	Mean left coronary flow, mL/min	Heart rate, bpm	Stroke volume, mL	Mean aortic pressure, mmHg	Mean left coronary flow, mL/min
	60	77.7±1.2	100.1±0.6	213.5±10.0	60	76.0±1.1	100.1±0.5	218.4±2.6	60	76.0±1.5	100.0±0.3	212.5±3.9
	60	76.3±0.8	100.2±0.2	210.1±5.8	60	79.0±1.1	99.9±0.2	211.5±5.7	60	77.0±1.0	100.1±0.1	211.5±8.1
	60	77.6±1.5	100.0±0.4	209.6±8.0	60	76.1±1.8	99.9±0.1	216.6±6.5	60	77.6±1.5	100.0±0.4	216.6±6.5
	60	77.3±1.5	100.4±0.3	210.5±6.3	60	77.3±1.5	100.0±0.4	214.4±1.6	60	77.3±1.5	100.0±0.4	214.4±1.6
	60	76.8±1.5	100.1±0.3	213.2±3.3	60	76.8±1.5	100.1±0.3	213.2±3.3	60	76.8±1.5	100.1±0.3	213.2±3.3
	60	76.4±1.5	100.1±0.3	213.2±3.3	60	76.4±1.5	100.1±0.3	213.2±3.3	60	76.4±1.5	100.1±0.3	213.2±3.3

P45

Multivariate Analysis of Left Ventricular Assist Device (LVAD) Patient Cohort: Mortality Predictors, Readmission Patterns, and Demographic Disparities

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Background: Based on the National Readmission Database (NRD), a multivariate analysis of 11,021 LVAD discharges (2016-2020) compared “alive” versus “dead” cohorts. The objective was to identify mortality predictors during the index admission, analyze readmission patterns, and elucidate demographic and comorbidity differences between the two cohorts.

Methods: Utilizing logistic regression models, baseline characteristics, comorbidities, and mortality predictors were examined. Significance was determined through p-values of <.05.

Results: The mortality rate among LVAD patients was 12.26%. Significant associations were noted with age at admission (Alive: 56.64, Dead: 60.87, P<.001), length of stay (LOS, # vs #, P<.0001), and primary payer (% vs %, P<.0001). Comorbidity differences highlighted higher prevalence among dead patients for congestive heart failure (Dead: 95.41%, Alive: 99.00%, P<.001), peripheral vascular disease (Dead: 30.50%, Alive: 45.83%, P<.001), and cerebrovascular disease (Dead: 24.28%, Alive: 9.75%, P<.001). Multivariate logistic regression identified age, LOS, primary payer, and specific comorbidities as significant mortality predictors (p< 0.05). 4.20% of patients were readmitted within 30 days, 30.12% within 90 days, and 45.81% within 180 days of the index admission. Causes included chronic kidney disease or heart failure, thrombosis, acute on chronic heart failure, and other LVAD-related complications.

Conclusion: This study comprehensively analyzes mortality predictors and readmission patterns among LVAD patients. The identified disparities contribute valuable insights for personalized care strategies and highlight areas for targeted interventions to improve outcomes in this complex patient population.

P46

Impact of the HeartMate 3 Pump Speed Modulation on Haemodynamics and Pump Parameters

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Background: The HeartMate 3 (HM3) continuous-flow left ventricular assist device (LVAD) employs an artificial pulse (AP) pump speed modulation algorithm. This consists of a decrease of pump speed by 2000rpm followed by an increase by 4000rpm (i.e. 2000rpm over set speed) over 350ms, repeating every 2 seconds, asynchronously with the heart. We sought to assess the impact of the HM3 AP mechanism on pump parameters and measured hemodynamic variables.

Method: A HM3 was attached to the left ventricle on a mock circulatory loop (MCL) based on a five-element Windkessel model. Experiments were performed at set speed of 5300rpm. Data on pulsatility index, pump power, pump derived flow, and calculated flow were collected first with AP turned off, then repeated with AP turned on. The experiments were performed at baseline and during variations in preload and afterload. Left ventricular end diastolic pressure (LVEDP) and mean arterial pressure (MAP) were used as surrogates for preload and afterload respectively. The effects of AP mechanism on parameters were analysed using the paired Wilcoxon signed-rank test.

Results: Experiments were performed at the following combinations of LVEDP & MAP: (baseline[BL], BL), (BL + 2.5mmHg, BL), (BL – 2.5mmHg, BL), (BL, BL + 15mmHg), (BL, BL – 15mmHg). There were no significant differences in pulsatility index (median = 6.18[IQR = 6.16-6.92] vs 6.40[6.30-6.47], p=0.31), pump derived flow (3.83[3.60-3.90] vs 3.90[3.80-3.90] L/min, p=0.20), and measured flow (2.97[2.96-3.26] vs 3.04[2.94-3.05] L/min, p=0.81) for AP on vs off (**Table**). There was a non-significant trend towards increased pump power for AP on compared to AP off (4.05[4.03-4.07] vs 3.63[3.63-3.63] W, p=0.06).

Conclusion: The HM3 AP did not significantly affect pulsatility index, pump derived flow, or measured flow at baseline or with simulated changes in loading. Notably, there was a non-significant trend towards increased pump power with AP on, suggesting the AP mechanism may increase power consumption of HM3.

		Pulse Index		Pump Power (W)		Pump Derived Flow (L/min)		Measured Flow (L/min)	
		No Pulse	Pulse	No Pulse	Pulse	No Pulse	Pulse	No Pulse	Pulse
Preload (LVEDP, mmHg)	Afterload (MAP, mmHg)								
BL	BL	6.30	6.92	3.63	3.98	3.90	3.60	3.04	2.97
BL + 2.5	BL	6.40	6.16	3.63	4.13	3.90	3.90	3.05	3.26
BL - 2.5	BL	6.47	6.18	3.63	4.05	3.80	3.83	2.94	2.96
BL	BL + 15	9.25	10.10	3.61	4.03	3.07	2.85	2.40	2.36
BL	BL - 15	4.08	4.49	3.63	4.07	4.60	4.38	3.54	3.47
p-value		0.31		0.06		0.20		0.81	

Abbreviations: BL, baseline; LVEDP, left ventricular end-diastolic pressure; MAP, mean arterial pressure.

NB: All experiments performed at 5300rpm.

P47

Plasma Free Hemoglobin and Endothelial Axis in Pulmonary Hypertension: Exploring the Interplay

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Background: Free hemoglobin (Hb) in plasma, resulting from mechanical damage to RBC within various extracorporeal support systems or due to transfusion reactions or metabolic diseases, becomes a pathogenic element contributing to numerous health complications. When exceeding its detoxification system capacity, it triggers intricate pathological reactions. Hb's actions, such as nitric oxide (NO) removal, autooxidation, and reactions with peroxides and lipids, generate radicals and active lipid mediators. Hb acts as a signaling molecule, activating redox and oxygen-regulated transcription factors. Hb poses severe pathological risks to vital systems, including cardiovascular, renal, neural, gastrointestinal, and coagulation. Elevated free Hb has been observed in patients with pulmonary hypertension (PH), considered a potential pathogenic mediator in the development of PH. This consideration is particularly due to its impact on endothelial cells (EC), the dysfunction which is a hallmark of PH.

Methods: The study aimed to determine the effect of free Hb on normal and ischemic (GSH-depleted) EC from the human pulmonary artery and lung capillaries. Human pulmonary artery (HPA) and human pulmonary microvascular (HPMV) ECs (Clonetics, San Diego, CA) were subcultured in EGM-2 BulletKit and EGM-2MV BulletKit medium, respectively, to confluence on cover slips and 6-well cell cultured plates in a humidified atmosphere of 5% CO₂ and 37°C. To mimic ischemia, EC were depleted of GSH by 24 hr treatment with 200 uM of BSO (L-buthionine-[S,R]-sulphoximine). Then, normal, and ischemic ECs were exposed to 0.2 mM of Hb and assessed for cellular redox state (GSH), NO scavenging, Angiotensin Converting Enzyme (ACE) activity, oxidative stress (8-isoprostane, TBARS), inflammatory response (nuclear factor NF-kappa B activation, expression of VCAM-1), and early and late apoptosis.

Results: Hb accelerated pro-oxidant, pro-inflammatory, and pro-apoptotic responses in both HPA and HPMV ECs, with heightened effects in GSH-depleted cells. HPMV produced more vasoconstrictive 8-isoprostane than HPA ($p<0.05$). GSH depletion alone induced slight NF-kappa B, while Hb treatment significantly activated this pro-inflammatory transcription factor in both EC types ($p<0.05$), especially in GSH-depleted cells ($p<0.01$). Hb-mediated expression of VCAM-1 appeared similar in both cell types and was redox-status dependent, correlating with the degree of NF-kappa B activation. In both cell types, Hb acted as a NO sink. Hb significantly increased ACE activity in HPMV compared to HPA ($p<0.05$) and was found to have pro-apoptotic potential in GSH-depleted HPA and HPMV ECs.

Conclusions: This study suggests that free Hb may be more toxic in ischemic subjects, accelerating pro-oxidant, pro-inflammatory, and pro-apoptotic responses in HPA and HPMV ECs. In addition to NO scavenging, Hb, by increasing vasoconstrictive 8-isoprostane production and activating ACE, may directly contribute to PH pathomechanism.

P48

Exploring the Diagnostic Potential of Echocardiography in Detecting Occult Cardiac Injuries After Penetrating Thoracic Trauma: A Diagnostic Accuracy Meta-analysis

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Background: Penetrating thoracic trauma can lead to occult cardiac injuries, a potentially life-threatening condition that often poses diagnostic challenges in stable patients. Despite its invasive nature, subxiphoid pericardiotomy is traditionally recognized as the diagnostic standard. While echocardiography is proposed as a non-invasive alternative, its comparative accuracy against the standard method is yet to be definitively determined. This study aims to evaluate the diagnostic accuracy of echocardiography in detecting occult cardiac injuries following penetrating thoracic trauma in stable patients.

Methods: A comprehensive literature search was performed across multiple databases, including PubMed, EMBASE, and Web of Science, to identify studies that compared echocardiography to subxiphoid pericardiotomy for detecting occult cardiac injuries in stable patients after penetrating thoracic trauma. Statistical analyses were conducted using the meta package in R software (version 4.0.3), facilitating the pooling of sensitivity, specificity, false-positive rate, diagnostic odds ratio, and positive and negative likelihood ratios, all with corresponding 95% Confidence Intervals (CI).

Results: The meta-analysis included four studies encompassing 492 patients, of whom 183 had confirmed cardiac injuries, and 309 were identified as non-injured. The pooled sensitivity of echocardiography, compared to subxiphoid pericardiotomy, was 84.2% (95% CI: 78.1-88.8%, I²=49.9%), and the specificity was 81.5% (95% CI: 26.4-98.2%, I²=94.3%). The false-positive rate was 18.5% (95% CI: 1.8-73.6%). The diagnostic odds ratio was 23.41 (95% CI: 1.84-296.98), with the positive likelihood ratio at 4.55 (95% CI: 0.58-35.23) and the negative likelihood ratio at 0.19 (95% CI: 0.11-0.34).

Conclusion: Echocardiography shows promise as a non-invasive method for identifying occult cardiac injuries after penetrating thoracic trauma, though its performance compared to subxiphoid pericardiotomy warrants cautious interpretation due to high heterogeneity in specificity and wide confidence intervals. Further high-quality studies are required to affirm these findings and assess echocardiography's potential as a standard diagnostic tool.

P49

Cardiac Transplantation in the Contemporary Era: is Status 1 Pre-transplant Extra Corporeal Membrane Oxygenator Associated with Worse Outcomes?

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Background: Since the introduction of the new allocation system by UNOS, more cardiac transplants have been performed off short-term left ventricular assist devices [LVAD], and Extra Corporeal Membrane Oxygenator [ECMO] support as Status 2 and 1 respectively. We studied the impact of this allocation system on the outcomes of transplants

Methods: Between January 2013 and June 2023, 27732 transplants were performed. Data was obtained from the UNOS database, analyzed using the SPSS 29.0 Statistical Package, and reported using means and standard deviations, or medians and inter-quartile ranges. Survival data and univariate predictors thereof were analyzed by the Kaplan Method using the log-rank test. Variables with $p < 0.1$ were entered into Multivariable Cox proportional hazards model to identify predictors of long-term survival, and reported as hazard ratios [HR, confidence intervals]

Results: In the cohort of 27732 patients, 7500 [27%] were females. 675 patients [2.4%] were on ECMO preoperatively [UNOS status-1]. Post-operative complications included stroke ($n = 928$, 3.4%), dialysis ($n = 3,638$, 13.4%), and acute rejection ($n = 5,214$, 19.2%). Survival in the entire cohort following transplantation was 96.7% at 30-days, $79 \pm 0.3\%$ at 5-years and $55.5 \pm 1.1\%$ at 10-years [Figure-1]. 10525 patients [38%] did not have any cardiac surgery previously, survival in this group was $61.4 \pm 1.8\%$ at 10-years. 17207 patients [62%] had previous cardiac surgery, including long-term LVADs, survival in this group was $52.4 \pm 1.3\%$ at 10-years postoperatively [$P < 0.001$] [Figure-2].

In the Cox proportional hazards model, predictors of worse survival included trans-pulmonary gradient [TPG] $> 15 \text{ mmHg}$ [HR 1.19 (1.1-1.3), $p < 0.001$], and prior cardiac surgery including LVAD [HR 1.38 (1.29-1.47), $p < 0.001$]. Interestingly, contrary to popular belief, ECMO prior to transplantation did not adversely impact survival [HR 1.1 (0.9-1.4), $p = 0.3$].

Conclusion: Since the introduction of the new allocation system by UNOS, more Cardiac transplants have been performed off ECMO and short-term left ventricular support device support as Status 1 and 2 respectively, which did not adversely impact long-term survival. In contrast, cardiac transplantation in patients who have high persistent TPG at the time of transplant, and those who have previously undergone cardiac surgery, including long-term LVAD support, is associated with worse long-term outcomes.

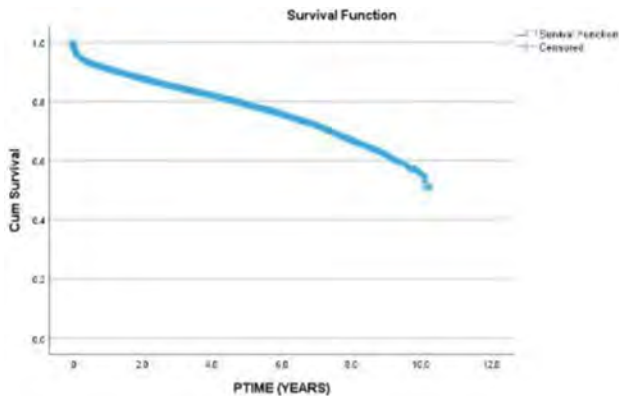


Figure 1. overall survival following heart transplantation

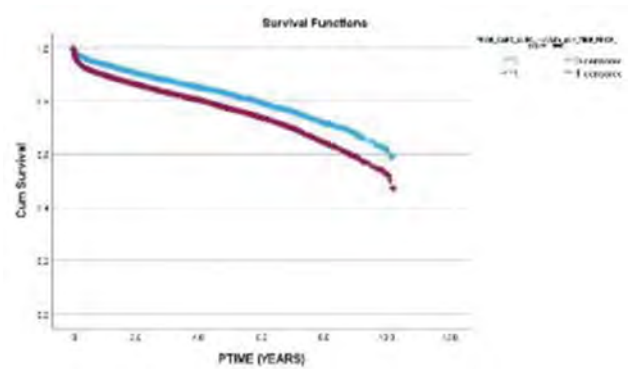


Figure 2. survival following heart transplantation in patients with no previous cardiac surgery and previous surgery including LVAD

P50

The Benefits of Total Parental Nutrition and Dialysis in Ex Vivo Lung Perfusion

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Background: Lung transplantation has proven to be an effective treatment for individuals with end-stage lung disease. However, a significant challenge arises as approximately 80% of donor lungs fail to meet the necessary clinical qualifications for transplantation, leading to their disposal. The development of ex vivo lung perfusion (EVLP) presents an opportunity to rehabilitate and recondition donor lungs, increasing the utilization rate of available donor organs. However, existing EVLP systems have certain limitations, including inadequate metabolic supplementation and a restricted preservation duration of approximately 12 hours. In addressing these limitations, we sought to investigate whether the incorporation of metabolic support through total parenteral nutrition (TPN) and a dialysis for waste clearance could improve lung oxygenation and extend the preservation period to 30 hours.

Methods: Three pairs of swine lungs were perfused using a custom-built EVLP platform for 30 hours. The experimental groups consisted of conventional clinical (CC) EVLP (control, n = 2) and enhanced EVLP with TPN and dialysis machine incorporated into the circuit (treatment group, n = 1). The lungs were ventilated with a PEEP of 5 mmHg, tidal volume of 6 mL/kg, and respiration rate of 10 breaths per minute. Blood flow was maintained at a target flow rate of 30% of estimated cardiac output. Physiological parameters including the oxygenation (P/F ratio), were continuously monitored, and lactate and ion concentrations were measured using an i-STAT blood analyzer.

Results: The inclusion of dialysis in the experimental group maintained lactate, glucose, and ion levels within physiological ranges compared to the control. The treatment group averaged around 2.61 ± 1.2 mmol/L whereas the standard EVLP lactate levels measured at 9.43 ± 4.1 mmol/L respectively. In addition, continuous infusion of TPN demonstrated improved oxygenation as evidenced with a P/F ratio of 662 as compared to the control group with a ratio of 500.

Conclusion: The integration of TPN resulted in more efficient oxygenation into the lungs, while dialysis effectively regulated lactate and ion levels. This improvement signifies a promising development in optimizing lung function during the preservation process, potentially extending the viability of donor lungs for transplantation. Additional trials are needed to prove the significance of the correlation between nutritional support and lung performance.

P51

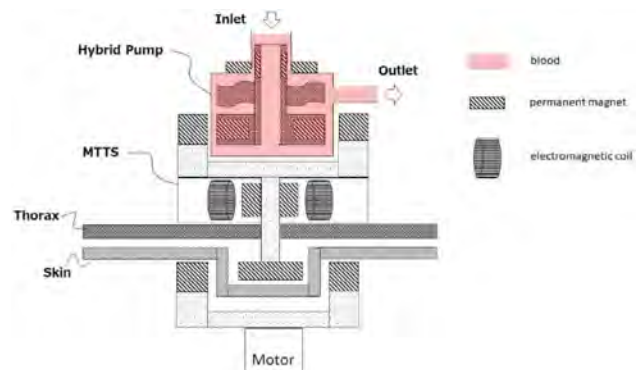
Improvement of a Magnetic-Electric Hybrid Wireless Left Ventricular Assist Device.

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Drivelines of the current left ventricular assist devices (LVADs) have some problems such as acting as a source of infection and limiting the outside activities of patients, thereby reducing the quality of life of patients. Transcutaneous energy transfer systems (TETSs) have been developed to solve these problems but they have other problems such as malposition between coils and burn injury due to sending high-power transmission. In a previous study, we proposed a magnetic-electric hybrid wireless LVAD to improve the current problems of conventional wireless LVAD, and conducted a bench-top feasibility test. However, both of the intracorporeal and extracorporeal devices of the hybrid wireless LVAD were too large and heavy to conduct an *in vivo* testing. In addition, power consumption of the hybrid wireless LVAD was much more than those of conventional LVADs. Moreover, no attempt was made to float an impeller of the hybrid wireless LVAD. Therefore, we improved our hybrid wireless LVAD to solve these problems.

First, we changed the position of the electromagnetic coils from the hybrid pump to a magnetic torque transmission system (MTTS) to shorten the distance between the electromagnetic coils and rotor magnets. Second, we changed the type of a permanent magnetic coupling (PMC) between the intracorporeal and extracorporeal magnets from the axial PMC to the radial PMC. Third, we introduced a magnetically levitated impeller using permanent magnets to reduce energy loss due to friction. These improvements enabled us to use smaller motors and magnets. As a result, the weight of the extracorporeal motor and magnets was reduced from 300 grams to 82 grams. In addition, the weight of the hybrid pump and MTTS was reduced from 149 grams to 99 grams. Moreover, power consumption was reduced by 47 percent from the previous hybrid wireless LVAD.

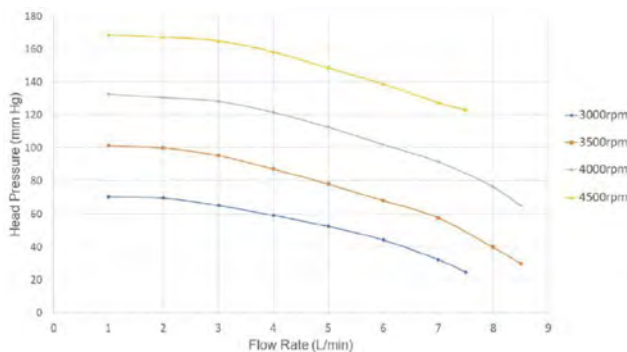
Our new hybrid wireless LVAD was successfully downsized enough to conduct in vivo testing and showed significant improvement of power consumption compared to the previous hybrid wireless LVAD. It has the potential to realize high quality of life of patients with LAVD. Our prospect for the near future is to conduct an *in vitro* hemolysis test and a subsequent *in vivo* testing.



Schematic cross section of the new magnetic-electric hybrid wireless left ventricular assist device.



Picture of the new hybrid wireless left ventricular assist device.



Pump performance curves for the new hybrid pump at speeds of 3000-4500 rpm. The fluid was a mixture of water and glycerin (60/40%). Comparison between the previous and new hybrid wireless LVAD

	Weight of the extracorporeal motor and rotating magnets (g)	Weight of the hybrid pump and MTTs (g)	Power consumption (W)
Previous	300	149	10
New	82	99	5.3

Power consumption was measured at a flow rate of 5.0 L/min and a head pressure of 80 mm Hg. Abbreviations: LVAD, left ventricular assist device; MTTs, magnetic torque transmission system.

P52

In Silico Investigation Of The Effect Of LVAD Cannula Design And Pump Unsteady Flow On The Hemodynamics Inside The Left Ventricle

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Background: To reduce the occurrence of thromboembolic events for patients implanted with LVADs third generation pumps include novel solutions, such as modified inflow cannulae and introducing device “pulsatility”. The effects of these innovations on the hemodynamics in the LV remain unexplored. This study aims at better characterizing the effect of cannula design and pump characteristics on intraventricular hemodynamics through a parametric approach.

Methods: Computational Fluid Dynamics (CFD) simulations were performed in a patient-specific left ventricle (LV), implanted with two different inflow cannulae: one protruding into the LV (HeartMate 3, Abbott) and one flushed with the LV endocardium (Evaheart 2, Evaheart). Unsteady flow waveforms were prescribed at the outlet of the cannula with the same time average flowrate (4.8 L/min), derived from experimental measurements for the HM3, and from a lumped parameter model that simulates the EH2 characteristic curves and the systemic pre and afterload. To assess the effects of the cannula design and the waveform independently, additional simulations were run keeping one parameter common and modifying the other: one with the HM3 cannula but the EH2 waveform and one with the EH2 cannula but the HM3 waveform. The aortic valve remained closed. The simulations were run for 10s, then, inertia-less tracers (mimicking the dynamics of platelets) were injected in the LV and tracked for 20 more seconds, or until they left the LV through the cannula. Velocity, Stagnation Index (SI) and platelet Residence Time (RT) were extracted from these simulations to identify potential thrombogenic regions in the LV associated with LVAD hemodynamics.

Results: LVAD implantation created a stagnation area in the LVOT under the closed AV. The protruding (HM3) cannula induced stagnation in the apical pocket. The EH2 characteristics curve led to larger temporal variations of the flowrate, due to higher sensitivity to preload. This resulted in higher values of SI (90% percentile) that were half the HM3 values. Similarly, the EH2 resulted in lower values of the 90% percentile of RT (-10% below the HM3). Finally, the results of the simulations keeping one parameter constant demonstrated that the predominant effect reducing stagnation is due to the EH2 preload dependency. It resulted in highly unsteady flowrate during the cardiac cycle, much higher than that induced by the HM3 speed modulation, while the cannula design played a much smaller role.

Conclusion: Our results suggest that larger temporal variations in LVAD flowrate, in this case induced by LVAD preload sensitivity, is the leading order mechanism to reduce stagnation in the LV, implanted with a centrifugal third generation LVAD. The design of the cannula clearly impacts stagnation at the apex; however, this effect is minor compared to unsteady flowrate.

P53

3D Printed Hydrogel-Based Synthetic Tissues for Cardiac Surgical Training

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Introduction: Synthetic cardiac models provide surgeons with the opportunity to practice techniques for complex cardiac procedures and receive tactile feedback, simulating a more realistic operation. Stereolithography has demonstrated the potential to fabricate these models at an affordable price point. This study aims to enhance the simulation of heart tissue mechanics through the use of 3D printed hydrogel resin blends.

Methods: Four hydrogel resin blends were used to create synthetic cardiac tissue with a Form2 stereolithography printer. 3Dresyn SAE1 was used as a base while 3Dresyn HA3 LV MF Bio and 3Dresyn Bioflex A10 MB Monomer Based were used as modifiers. Hydrogel resin blends were evaluated against fresh cardiac tissue in terms of puncture resistance, suture retention, and tensile strength using an AEL universal testing machine and a PCE-DFG N 20N force gauge (Figure 1A). Statistical significance was determined through a one-way ANOVA test with Tukey's HSD ($\alpha=0.01$).

Results: Data revealed no statistical differences ($p=0.07$) between puncture resistance values for the four hydrogel resin blends and cardiac tissue (Figure 1B, left). All hydrogel blend values for suture retention were statistically different from cardiac tissue ($p<0.01$), except for the 5% HA3 blend ($p=0.24$) (Figure 1B, center). The tensile strength values for the 2.5% HA3 and 5% HA3 blends were statistically different from cardiac tissue ($p<0.01$), while the values of the 1% HA3 ($p=0.98$) and 2% Bioflex ($p=0.99$) blends were not statistically different from cardiac tissue (Figure 1B, right).

Conclusion: While the 5% HA3 blend provides adequate suture retention, the 2% Bioflex blend not only offers adequate tensile strength, but improved tactility and increased resistance to rupture upon handling. Percentage adjustments of the 2% Bioflex modifier and incorporation of resin fine-tuners should be considered to improve suture retention. Further modifications to the blends should be made to better mimic cardiac tissue and reduce printing time.

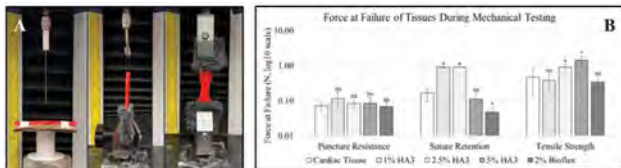


Figure 1. (A) Testing setup for puncture resistance, suture retention, and tensile strength (B) Mechanical testing results

P54

Reoperative Ventricular Assist Device Insertion for Patients with history of coronary artery bypass grafting: Less invasive approach versus full sternotomy

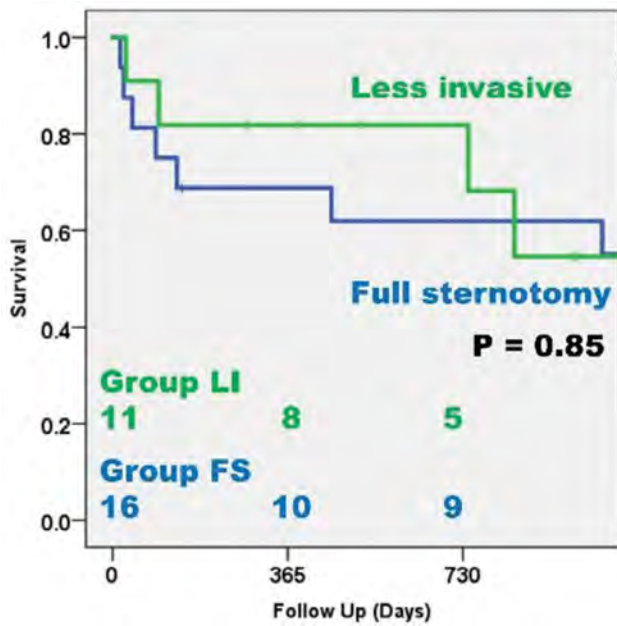
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Purpose: Reoperation for durable left ventricular assist device (LVAD) insertion following coronary artery bypass grafting (CABG) is challenging due to potential risk of injury to bypass grafts, great vessels, or the right ventricle (RV). We sought to analyze if less invasive approach for LVAD implantation may improve outcomes by minimizing dissection around the heart, potentially reducing bleeding, graft injury, or RV failure.

Methods: Between Mar. 2012 and Apr. 2023, 27 patients with history of CABG received reoperative LVAD insertion; 16 patients underwent a redo full sternotomy (Group FS) and 11 patients had less invasive approach (Group LI). The LI approach, initiated in May 2019, involves an inverted-T upper hemisternotomy at the level of the 2nd or 3rd intercostal space, dissection along the chest wall into the left pleural space, anastomosis of inflow cuff incorporating pericardium via a left thoracotomy in the 5th or 6th intercostal space, routing the outflow graft through the left pleural space, and outflow graft anastomosis to the ascending aorta. Either ascending aorta or axillary artery was used for arterial return and femoral vein was percutaneously cannulated.

Results: The median ages in Groups FS and LI were 68 and 70 years, respectively ($P=0.83$), with a median duration of 96 [24, 192] months since the last cardiac surgery. Six patients had preoperative veno-arterial extracorporeal membrane oxygenation support (Group FS, 18.8% [N=3] vs. Group LI, 27.3% [N=3], $P=0.662$). Heartmate 2 was exclusively used in FS group (FS, 56.3% [N=9/16] vs. LI, 0%), while HeartWare was predominantly used in group LI (FS, 31.3%, [N=5/16] vs. LI, 63.6% [N=7/11]). Heartmate3 was used in 6 patients. Left internal mammary artery graft was patent in 23 patients (85.2%). None of patients had injury of bypass graft. Concomitant procedure was performed in 5 patients in FS group (aortic valve, N=3, and tricuspid valve, N=2). In isolated LVAD implantation, cardiopulmonary bypass time was comparable between groups (FS, 75 [68, 96] min vs. LI, 67 [58, 89] min, $P=0.33$). The rate of severe RV failure requiring mechanical support was higher in FS groups (FS: 43.8% [N=7] vs. 0%, $P=0.02$). Patients who underwent concomitant procedures in FS group did not develop RV failure. Hospital mortality (FS: 31.3% [N=5] vs. LI, 9.1% [N=1], $P=0.35$), the rates of tracheostomy and hemodialysis were numerically higher in Group FS. One-year estimated survival was not significantly different (FS: $68.8\pm11.6\%$ vs. LI, $81.8\pm11.6\%$, $P=0.85$).

Conclusions: Less invasive reoperative LVAD insertion may have a potential to reduce RV failure and improve outcomes in patients with history of CABG compared to FS approach.



Characteristics of reoperative LVAD in patients with previous history of CABG

	All N=22	Full Sternotomy N=16	Less Invasive N=11	P-value
Age	67 [58, 74]	68 [61, 77]	70 [58, 75]	0.83
Male	24 (88.9%)	15 (93.8%)	9 (81.8%)	0.55
Duration from last cardiac surgery, months	87 [21, 183]	114 [8, 201]	73 [33, 192]	0.94
Patent LIMA-LAD	23 (85.2%)	14 (87.5%)	9 (81.8%)	1.00
LVAD off pre-op VA-ECMO	6 (22.2%)	3 (18.8%)	3 (27.3%)	0.66
Device				0.009
Heartmate II	9 (33.3%)	9 (56.3%)	0	
HeartWare	12 (44.4%)	5 (31.3%)	7 (63.6%)	
Heartmate 3	6 (22.2%)	2 (12.5%)	4 (36.4%)	
Outcomes				
Cardiopulmonary bypass time in isolated LVAD, min	73 [63, 92]	75 [68, 96]	67 [58, 89]	0.33
Concomitant procedure	5 (18.5%)	5 (31.3%)	0	0.06
RV failure requiring MCS	7 (25.9%)	7 (43.8%)	0	0.02
In-hospital mortality	6 (22.2%)	5 (31.3%)	1 (9.1%)	0.35
Reoperation for bleeding	6 (22.2%)	4 (25%)	2 (18.2%)	1.00
Stroke	3 (11.1%)	1 (6.3%)	2 (18.2%)	0.55
Renal replacement therapy	7 (25.9%)	6 (37.5%)	1 (9.1%)	0.18
Tracheostomy	13 (48.1%)	10 (62.5%)	3 (27.3%)	0.12

MCS: mechanical circulatory support, RV: right ventricle, VA-ECMO: veno-arterial extracorporeal membrane oxygenation

P55

Systematic review of sex differences in LVAD recovery and outcomes

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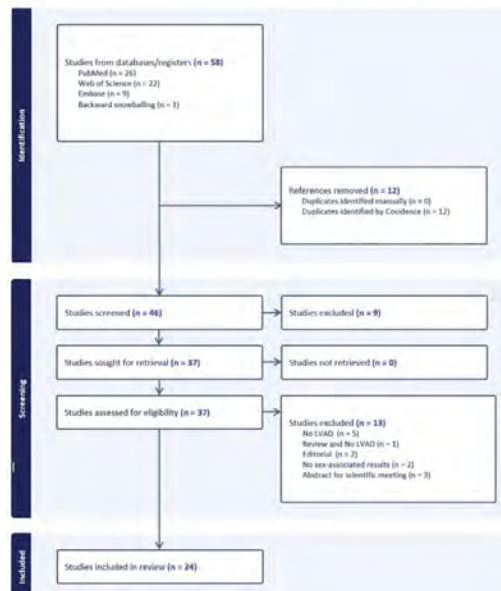
Introduction: Left Ventricular Assist Devices (LVADs) are a pivotal therapeutic option for end-stage heart failure patients awaiting heart transplantation or for destination therapy. Despite the increasing utilization of LVADs, women account for less than 25% of LVAD recipients, who tend to be older at time of placement. There remains a shortage of research on potential gender-specific differences in outcomes, particularly in achieving recovery after LVAD implantation. The purpose of this systematic review was to synthesize evidence in the literature of sex differences in post-LVAD outcomes, specifically recovery, adverse events and survival as well as identify sex-associated predictors.

Methods: A comprehensive electronic search of PubMed, Embase, and Web of Science databases was performed. To account for varying definitions and assessments of LVADs, outcomes and sexes, a broad set of search terms and MESH headings were utilized. The search included all articles published within 10 years of January 2024. Covidence© software was used for article extraction, screening, and selection in accordance with PRISMA guidelines. Studies were included if they reported differences in LVAD outcomes comparing men and women. Exclusion criteria are shown in Figure 1. PRISMA Diagram.

Results: From the 58 initially obtained, 24 studies met inclusion criteria. A total of 189,511 patients were included, with women comprising 26.2% (n = 49,641) of the combined cohort. 16.6% (n = 4) of studies reported sex-based recovery outcomes, with a trend toward increased recovery rates among women. 66.6% of studies (n=16) reported post-LVAD outcomes by sex, with 11 reporting significant survival differences. Three articles reported completely null findings for sex differences in outcomes. Data analysis from full-text review is still in progress.

Conclusion: Women remain underrepresented in LVAD literature, particularly when examining post LVAD recovery. There is emerging evidence suggestive of significant sex differences in non-survival outcomes, with a trend towards women having a higher frequency recovery compared to men. However, there is a paucity of data on sex differences in recovery metrics. Identifying these disparities and sex-associated predictors could inform future research to optimize post-implantation recovery and outcomes equitably among men and women.

LVAD systematic review



P56

A Comprehensive Review of Challenges and Failures Related to the Use of Tubing with Extracorporeal Devices

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Introduction: Extracorporeal tubing is widely used in mechanical circulatory support, specifically Extracorporeal Membrane Oxygenation (ECMO), Ventricular Assist Device, cardiopulmonary bypass, and while not a cardiovascular life support, dialysis. The devices all incorporate blood-contacting tubing, which is known to have a high predisposition to thrombus formation. In order to combat this complication, many solutions have been developed, ranging from a coating for the tubing lumen to changing the material of the tubing itself. However, each solution is met with its own challenges, as the inherent risks associated with blood-contacting devices remain. In addition to the already problematic clot formation, the integrity of the tubing over time has also been brought to attention as some have seen the tubing fail with increased duration/use of these devices.

Methods: Through a literature review, the different locations of common thrombus formation were evaluated. Papers included in the analysis were chosen based on keyword matches, such as "extracorporeal tubing failures" and "ventricular assist device and clots" to name a few.

Results: In general, for extracorporeal devices, the most common area of interest was the interface of the tubing with the medical device, and any points of tubing-to-tubing attachments where the laminar flow of blood may be disrupted. Additionally, this review highlighted the connection point of the tubing to the medical device as the most common point of tubing fatigue that could result in tubing failure, and in some cases, large amounts of blood loss. In the case of extracorporeal VADs, it was found that the location that causes the greatest buildup of thrombus would be at the junction between the cannula of the pump to the extracorporeal tubing (Figure 1). This buildup was commonly seen on both the inflow of the pump and the outflow of the pump. However, in a few cases white thrombus or buildup was seen at random throughout the tubing. During this review it was also noted that fractures of the tubing, although rare, may occur at the intersection between the metal cannula of the pump and the start of the extracorporeal tubing (Figure 2).

Conclusion: With longer implant times/lifetime of devices that use extracorporeal tubing, a closer look must be taken at the effects increased use may have on this crucial component of the device. Across all devices that use blood contacting extracorporeal tubing, a common location of thrombus formation was found to be the junction between the medical device and the tubing. Interfaces that also include a more rigid metal cannula may be at risk for tubing fatigue, and warrants further analysis to prevent a catastrophic device failure. Future work must be directed toward monitoring tubing integrity throughout the lifetime of the device, increasing the structural integrity of the tubing/cannula interface, as well as finding new ways to monitor and prevent the build up of thrombus formation.



Figure 1. Generalized figure of a thrombus formation at the junction of the cannula and the tubing.

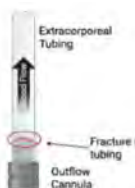


Figure 2. Depiction (due to proprietary data) of a fracture at a tubing site of interest.

P57

Histological Evaluation of a Synthetic Vascular Graft: Integrating Paraffin and Plastic Histology Techniques

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Background: Paraffin histology is a standard technique used in preclinical research to microscopically evaluate tissues. In this study, paraffin histology was used to analyze a new polyester graft device (Diaxamed, Greenville, SC) implanted in an aortic sheep model; the areas of interest include the capsule around the graft, the interphase of capsule and graft, and the blood-contacting surface. This study aimed to evaluate the overall host response to the implanted device and establish device safety.

Methods: Histological sectioning of the graft using traditional techniques was challenging as the graft would fracture when cut with the microtome. In order to significantly decrease difficult sectioning and sectioning waste, the tissue sections were bisected before microtomy. This only partially helped but still resulted in paraffin sectioning artifacts. The microanatomy was still able to be interpreted, but the presence of artifacts made it difficult to fully analyze the target tissues. Therefore, in order to validate the paraffin histology predictions, one tissue section of mid-graft underwent plastic histology, where the tissue/graft was infiltrated with Technovit 7200™, polymerized under ultraviolet light, sectioned with a diamond blade, micro-ground down to a 60-micron thick section, and then stained with HE.

Results: Plastic histology resulted in decreased sectioning artifacts of the graft. The lumen of the graft was verified to be patent and endothelialized. With paraffin histology alone, the interphase of the capsule and the graft, as well as the blood contact surface, were not always present due to the sectioning artifact. Plastic histology provided an intact section that accommodated a full assessment of the outer capsule and pseudo intima, allowing for verification of paraffin histology's preliminary results (Figure 1).

Conclusion: The integration of paraffin and plastic histology techniques provided an overall complete assessment of the graft. While paraffin histology has the benefits of being faster and less expensive, it can often result in artifacts that can preclude a full histological analysis. Plastic histology, while providing alternative options to decrease sectioning artifacts, is a much longer process and can be more expensive to perform.

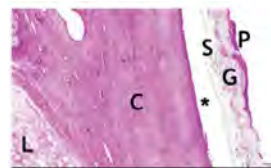


Figure 1. Transmural section of control graft (HE) at 1, 30, and 90 days. C: Capsule, G: Graft fibers, P: Pseudointima, L: Lung

P58

Methodology to Assess Anatomical Fit of Transvalvular Left Ventricular Micro-Axial Flow Pumps in Adult Congenital Patients

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Background: The population of adult congenital cardiac patients is growing as pediatric survival increases. Physicians have increasingly elected to use the Impella platform for adult congenital patients in need of mechanical circulatory support. While Impella devices were developed based on normal patient anatomy, congenital patients have been successfully supported provided proper device fit. Pre-evaluation of non-standard cardiovascular anatomy caused by underlying etiology and resultant treatments can inform device selection for successful Impella placement and support.

Methods: Key anatomic features that influence Impella delivery and positioning were identified in collaboration with clinicians. A workflow was developed to assess congenital patient anatomy beginning with 3D anatomic reconstruction from contrast-enhanced, cardiac gated CT scans using commercially available CT-scan reconstruction software. This workflow was developed on CT scans from Impella supported congenital cardiac patients and the resultant reconstruction and measurement suite was then iteratively reviewed with clinicians to refine and refocus the assessment.

Results: To assess for potential transvalvular fit in an adult congenital patient, ventricle and ascending aorta lengths were measured from the valve plane. Minimum diameters were measured from the ascending aorta through the brachiocephalic, subclavian, and axillary arteries out to the thoracromial artery ostium. CAD models of Impella devices were positioned in the 3D anatomical reconstruction to aid in visualization of potential patient fit.

Conclusions: This user-validated workflow supports efficient, protocolized assessment of adult congenital patient anatomy for Impella fit. Collaboration between engineering and clinicians can develop strategies and tools to assess potential device use in unique patient anatomies and inform plan of care and device selection.

P59

Video Quantitative Motion Analysis for Patients with Arthritic Diseases: A New Methodology for Remote Precision Medicine and Telehealth

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Purpose: Restrictions on in-person contact facilitated by the coronavirus pandemic paved the way for a newer form of patient-physician interaction. Telehealth not only provides a way to accommodate these restrictions but also serves as an attractive means of receiving medical care for individuals with reduced mobility. Frequently, these individuals consist of patients afflicted with various forms of arthritis. Arthritis results in chronic joint inflammation within patients, thereby affecting their day-to-day functionality due to the present stiffness, swelling, and pain within joints across the body. As a result, patients experience a reduced range of motion (ROM). To study and monitor the progression of arthritis within patients, it is critical that physicians can quantitatively track and analyze changes in patient ROM. Previously, our group developed a digital system that can record motion using mobile devices (MOCA) that can be effectively used either at home or in a clinic. In this study, we aim to test the applicability of MOCA in detecting and monitoring the abnormal range-of-motion (ROM) of individuals affected by various forms of arthritis. We hypothesize that MOCA will provide accurate quantitative data about joint mobility, thereby facilitating a better assessment of arthritic disease progression in patients.

Methods: One cm² brightly-colored visual markers were placed on healthy subjects and those self-reporting clinically diagnosed arthritis at specific anatomical locations on the body to accurately collect motion data and define the motion signature of each respective joint. Video technology (MOCA) recorded the angle at the joint in degrees as participants performed 15 trials of each of 11 defined motions. These angles were graphed, yielding the motion signature. The absolute value of the difference between the maximum and minimum ROM was extracted and compared between healthy and arthritic subjects.

Results: MOCA technology successfully recorded the ROM for the 11 motions included in both healthy (n= 16, 11F & 5M) and arthritic subjects (n= 17, 15F & 2M). A clear difference was detected between the range of motion of the tibiofemoral and talocrural joints in comparing healthy and arthritic subjects.

Conclusion: The MOCA video motion analysis system can accurately characterize and track the movement of joint motion and detect and quantitate differences between healthy and arthritic subjects. This technology, when applied in clinical settings, has the potential to provide a quantitative method to track ROM over time, virtually, providing physicians with additional insights into arthritic disease progression. With more patients and physicians preferring telehealth visits for safety and convenience, this technology has the potential to expand the capabilities of these visits by enhancing the precision of the evaluation and care for innumerable patients suffering from arthritis.

	Average Range of Motion for Healthy Subjects (degrees)	Average Range of Motion for Arthritis Subjects (degrees)
Talocrural Joint	54.71	32.20
Tibiofemoral Joint	69.94	59.33

P60

The Role of Artificial Intelligence in Interpreting Myocardial Perfusion Imaging: A Diagnostic Accuracy Meta-Analysis

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Background: Artificial Intelligence (AI) has opened up exciting new avenues in cardiovascular imaging. Myocardial Perfusion Imaging (MPI), a crucial non-invasive diagnostic tool for coronary artery disease, traditionally depends on reader expertise, which could lead to variable diagnostic accuracy. AI has emerged as a promising alternative to enhance the diagnostic performance of MPI. This study aims to evaluate the diagnostic accuracy of AI algorithms in the interpretation of MPI and compare it with conventional expert readers.

Methods: A systematic review and meta-analysis were conducted on studies that compared AI with expert readers for MPI interpretation. Data were sourced from Medline, Embase, Cochrane Library, and other databases from inception to September 2023. The comparator index test was conventional expert readers, with coronary angiography serving as the reference standard for detecting coronary artery disease. Statistical assessments were undertaken using R software (version 4.0.3) with the mada package, enabling the pooling of estimates for sensitivity, specificity, diagnostic odds ratio, and both positive and negative Likelihood Ratios (LRs), which are reported within a 95% Confidence Interval (CI).

Results: Our analysis included six eligible studies involving a total of 2,922 patients. The pooled analysis revealed that AI algorithms, when employed for MPI interpretation, demonstrated a sensitivity of 75% (95% CI: 69.9%-79.6%, I²=85.2%), specificity of 74% (95% CI: 64%-82.1%, I²=93.5%), the false-positive rate of 26% (95% CI: 17.9%-36%), the diagnostic odds ratio of 8.57 (95% CI: 4.99-14.71), positive LR of 2.89 (95% CI: 2.02-4.13), and negative LR of 0.34 (95% CI: 0.26-0.42).

Conclusion: The results indicate that AI demonstrates promising diagnostic potential in interpreting MPI, with a marked performance improvement over conventional expert readers. However, further large-scale and rigorous studies are necessary to validate these findings and explore the potential of integrating AI into standard clinical practice.

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Evaluating Vascular and Bleeding Risks of Vascular Closure Devices in Transfemoral Transcatheter Aortic Valve Replacement: A Network Meta-Analysis

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Background: Transfemoral transcatheter aortic valve replacement (TAVR) has become a feasible option for high-risk patients with severe aortic stenosis, despite potential vascular and bleeding complications that can impact patient outcomes. Vascular closure devices (VCDs) have been proposed to mitigate these complications, but the comparative efficacy and safety of these different VCDs remain to be established. This study aims to evaluate and compare the rate of vascular and bleeding complications associated with VCDs.

Methods: A systematic literature search was conducted in PubMed, Embase, and Web of Science until December 2022, focusing on studies comparing MANTA, ProGlide, and Prostar VCDs in transfemoral TAVR. Using netmeta package in R software, we conducted a network meta-analysis applying random-effects models and using Odds Ratio (OR) as an effect estimate for the specified outcomes.

Results: The meta-analysis included 15 studies with 1,038 patients in the MANTA, 4,688 in the ProGlide, and 3,425 in the Prostar studies. The treatment ranking was as follows: MANTA, ProGlide, and Prostar. When compared to MANTA as a reference, there was no significant difference in major vascular complications in ProGlide (OR=0.85, 95% CI: 0.41; 1.75) and Prostar (OR=0.39, 95% CI: 0.03; 4.75). In terms of minor vascular complications, no significant difference was observed among the three devices compared to MANTA, with ProGlide yielding an OR of 0.87 (95% CI: 0.52; 1.46) and Prostar an OR of 0.54 (95% CI: 0.20; 1.45). No significant differences were found in the device failure rate compared to MANTA, where ProGlide yielded an OR of 0.82 (95% CI: 0.32; 2.15) and Prostar an OR of 1.49 (95% CI: 0.15; 14.67). Prostar showed a desirable and lower rate for the severe bleeding rate, albeit not significantly different from MANTA (OR=0.68, 95% CI: 0.49; 0.95) and Prostar 0.68 [95% CI: 0.49; 0.95].

Conclusions: Our study sheds new light on the comparable effects of various VCDs on vascular and bleeding complications post-TAVR, with no significant differences noted across the three devices. Due to the limited comparative studies, further large-scale, randomized controlled trials are essential to reinforce these findings and inform VCD usage guidelines in TAVR.

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Normal Ventricular Function and Geometry Following Survival After One Week of Non-Blood Contacting Biventricular Support for Cardiogenic Shock

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Purpose of Study: Direct mechanical ventricular actuation (DMVA) employs a pneumatically regulated, silicone device to transfer systolic and diastolic pump function to the ventricular myocardium. Unlike direct cardiac compression (DCC) devices, DMVA augments ventricular filling. The device has been successfully used in humans. This report reviews recent data from a patient who recovered following over one week of DMVA support.

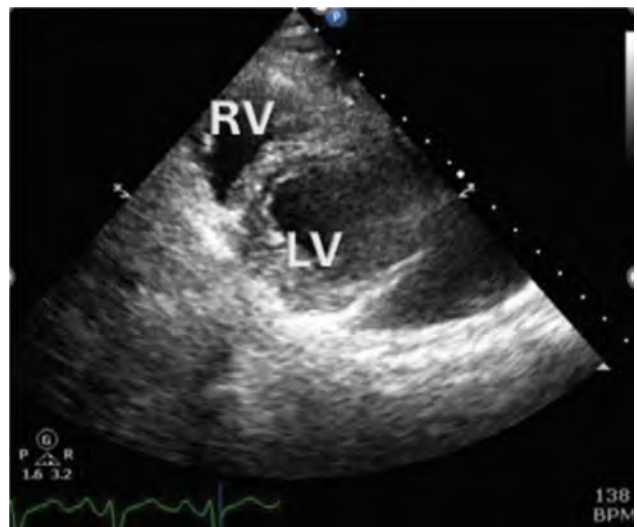
Methods Used: A clinical trial at Duke University Medical Center for use of DMVA began in 1990. Cardiac transplant candidates experiencing cardiogenic shock refractory to medical management were eligible for DMVA. After informed consent, the device was applied via a left anterior thoracotomy or median sternotomy. Device sizes ranging from 90 mm to 120 mm diameter were utilized. Pneumatic drives regulated pump parameters and vacuum attachment. Intra-operative echocardiography (ECHO) and hemodynamic monitoring assessed device functionality. One patient receiving DMVA for acute viral myocarditis underwent echocardiographic assessment.

Results: An 18-year-old female presented in acute cardiogenic shock due to an acute viral myocarditis. She was brought to the operating room after informed consent. At the time, she was in a state of severe pulmonary edema and experienced cardiac arrest prior to skin incision. Utilization of a fully silicone DMVA device allowed implantation through a small thoracotomy resulting in immediate return of near-normal hemodynamics. The patient's pulmonary edema resolved during the first 24 hours of support. On day 7, heart recovery appeared acceptable for device removal. Following 7.5 days (182 hours) of support, the patient was taken to the operating room, and the device removed. The patient's heart exhibited adequate heart function and the device removed on low dose dopamine. Her chest was closed and Dopamine weaned over the next 24 hours. She was discharged from the hospital two weeks later. She remains in good health with no device-related complications or physical limitations. Recent stress echocardiography confirmed normal right and left ventricular wall dimensions and function, normal valve function, with well preserved exercise-induced cardiac reserve. (See Fig 1 & 2).

Summary: These results demonstrate the return of normal cardiac function and functional reserve in a patient supported for over one week with DMVA. The results provide further evidence indicating the efficacy of DMVA for supporting the severely failing or arrested heart. DMVA can acutely return normal hemodynamics using atraumatic, non-blood contacting support. Diastolic augmentation is a highly unique feature which enables effective biventricular support. Physiology pulsatile hemodynamics, lack of blood contact and no need for anticoagulants are other unique attributes. Current efforts are being directed toward short term post-cardiotomy support and a minimally invasive concept.



Transthoracic echo demonstrating normal left atrium (LA) and left ventricle (LV).



Transthoracic echo demonstrating normal right ventricle (RV) and left ventricle (LV).

P63

Ultrasound-Guided Thrombolysis: A Non-Invasive Approach for Deep Vein Thrombosis Resolution

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Deep Vein Thrombosis (DVT) presents a considerable health threat, carrying potential complications like pulmonary embolism (PE) and chronic venous insufficiency (CVI). The emphasis of this study centers on utilizing ultrasound-guided thrombolysis as a non-invasive and efficient approach for eliminating deep vein thrombi.

The study employs advanced ultrasound imaging techniques to visualize and precisely target the thrombus within deep veins. Through the use of thrombolytic agents, such as tissue plasminogen activator, delivered directly to the thrombus under ultrasound guidance, the treatment aims to dissolve the clot, restoring normal blood flow and preventing further complications.

Clinical trials and case studies have demonstrated the efficacy and safety of ultrasound-guided thrombolysis in Deep Vein Thrombosis resolution. The non-invasive nature of the procedure minimizes the risk of complications associated with traditional surgical interventions, making it a promising alternative for patients with contraindications to surgery or those seeking less invasive treatment options.

This work discusses the underlying principles of ultrasound-guided thrombolysis, including real-time monitoring of the thrombus dissolution process and the potential for reducing the risk of post-thrombotic syndrome. Additionally, it addresses the importance of patient selection, optimal dosing of thrombolytic agents, and the ongoing research efforts to further refine this approach.

In conclusion, ultrasound-guided thrombolysis emerges as a promising and minimally invasive strategy for the removal of deep vein thrombosis, offering a safer and more effective alternative to conventional treatments. The integration of advanced imaging technologies with thrombolytic agents represents a significant advancement in the field of vascular medicine, providing a potential paradigm shift in the management of Deep Vein Thrombosis.

Key Words: Bioengineering, Deep Vein Thrombosis, Ultrasound-Guided Thrombolysis, Pulmonary Embolism, CVI

P64

Effects of Pulsatile Flow and Paravalvular Leak flow around TAVI model on Thrombus Formation by Computational Fluid Dynamics and Optical Visualization in Vitro

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Background & Aims: There is a possibility of high risk of thrombus formation by leakage (PVL; paravalvular leak) flow around TAVI (Transcatheter Aortic Valve Implantation). To find out the mechanism of thrombus formation by this leakage flow is important issue. In our previous studies, effects of the high shear rate on the thrombus formation rate at wall on orifice flow were examined by observation of thrombus formation using laser sheet, and it was found that the thrombus formation rates increase with the high shear rates at the wall. As the flow should be pulsatile in actual cases, it is also necessary to find out effect of pulsatile flow on thrombus formation at this leakage flow of the valve. In this study, to investigate effects of pulsatile flow on the thrombus formation around TAVI models including leakage flows, shear stress distribution history on the wall will be obtained computational fluid dynamics and compared with the results of thrombus formation by laser sheet in vitro.

Method: As experimental objects, there are orifice pipe and the leakage models for observation of thrombus formation. Each leakage size h is 0mm, 0.5mm, 1mm respectively with 20 mm diameter with stenosis. The target flow filed with fresh blood plasma of pigs is observed with highspeed CCD camera by laser sheet. After observation of thrombus formation with pig plasma, pressure histories at inlet and outlet are obtained with water at 5 l/min (Fig.1). As for CFD works with Ansys Fluent, the measured pressure at inlet and outlet (Fig.2(a)) are given as the boundary conditions.

Results and Conclusion: As for CFD results, Fig. 2(b) shows typical distribution of wall shear stress at 0.95 s in case of $h=0, 0.5, 1$ mm. Due to the increasing of leakage size, area of high wall shear stress is increasing, but there is a peak area of high wall shear stress at $h=0.5$ mm. After the peak area at $h=0.5$ mm, it is decreasing at $h=1.0$ mm. The large area of high wall shear stress indicates the high averaged wall shear stress per area. By considering the time history of the pulsatile flow and integrating the averaged wall shear stress with periodical time, it can be evaluated as the high averaged wall shear stress per area and time. From this result, it is found there is a peak of averaged wall shear stress while the leakage size is increasing. This tendency is like the starting time of thrombus formation with leakage from 0.0 mm to 1.0 mm in the previous results of observation of the thrombus formation. From this new finding, it is concluded that starting time such as ACT (Activated Clotting Time) can evaluated by wall shear stress. In future, effects of frequency on the thrombus formation should be investigated as the pressure history of pulsatile flow includes high frequency components.

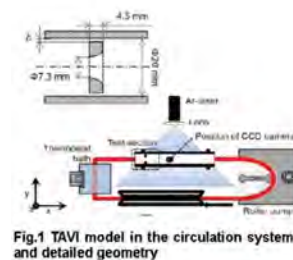


Fig.1 TAVI model in the circulation system and detailed geometry

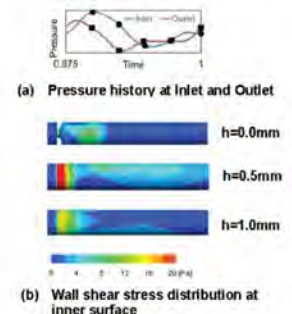


Fig.2 Pressure history by measurement and typical results of wall shear stress distribution by CFD

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The Wired Room 2.0: Automated Digital Sound, Image, and Motion Analysis for Enhanced Medical Diagnostics from A Patient Encounter

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Background: In-person clinical encounters, between patients and physicians, produce information that guides the delivery and accuracy of care. However, patient encounters have become increasingly shorter due to the requirements of electronic health record data entry and the use of a computer by the physician. Patient information, such as voice, action, and behavior, is often lost or never recorded. The Wired Room 2.0 system was developed to capture this lost information and supplement in-person health encounters with real-time audio and visual data capture. This project is a follow-up to last year's Wired Room but with an emphasis on audio data capture and analysis. We also test the novel concept of extracting and analyzing "biomarkers" from the captured patient data to detect physiological abnormalities that can be overlooked or missed using an artificial intelligence model.

Methods: A Python-based sound analysis program was developed that accomplishes multiple goals. It records signal components of the patient's voice and lung sounds and provides a statistical analysis based on past visits. The system uses voice diarization techniques to differentiate between the provider and patient for audio analysis. Stethoscope audio analysis utilizes a deep neural network trained and tested on ICBHI 2017 for detection of lung sounds that can detect abnormalities such as crackles and wheezes in the collected lung sounds. A software system developed by Google - Google MediaPipe is used to detect and save joint angles and angular acceleration of the patient.

Results: The Wired Room 2.0 has an emphasis on audio data collection, analysis, and biomarker extraction. The following biomarkers are currently able to be successfully extracted from an audio signal: harmonic to noise ratio (HNR), noise to harmonic ratio (NHR), spectral entropy (SE), short time energy (STE), zero crossing rate (ZCR), spectral roll off (SR), spectral centroid (SC), and spectral flux (SF). The system is capable of producing a graphical statistical analysis of each digital biomarker for each patient that allows for comparison of values between different patient visits.

Conclusion: The Wired Room 2.0 has successfully developed a portable smart room kit that uses cameras, microphones, and a digital stethoscope to extract quantitative motion and audio data that can be used for further analysis. The system contains a very easy-to-use GUI that will allow providers to collect quantitative data from their patient interactions. Current developments are aimed towards measurement of performance in speaker diarization and lung sound abnormality classification using AI trained algorithms. The system improvements will offer thorough quantitative audio analysis, complementing the existing motion analysis to enhance medical decision-making.

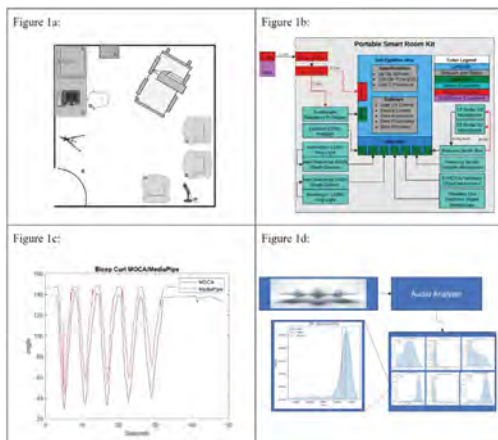


Figure 1. a: Room configuration. Figure 1b: System block diagram. Figure 1c: Joint angle analysis. Figure 1d: Audio biomarker analysis

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In-Vitro Evaluation of India-US (INDUS) Magnetically Levitated Blood Pump

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Purpose of Study: Increasing rate of heart failure and shortage of donor hearts in India have made the development of ventricular assist devices (VAD) more prominent. One such attempt is ongoing in Hyderabad, India towards the development of a low-cost indigenous blood pump named INDUS: a magnetically levitated extracorporeal blood pump that can serve both, as a Left Ventricle Assist Device (LVAD) as well as an Extracorporeal Membrane Oxygenation (ECMO) blood pump. It is designed to be fully compatible with the widely used CentriMag[®] motor and controller. The purpose of this study is to conduct in-vitro hydrodynamic testing and compare the INDUS pump prototype with the CentriMag[®] pump as a benchmark.

Methods: A rapid prototype of the INDUS pump was developed by SLA 3D printer using a photopolymer resin. It consists of a top housing, bottom housing, impeller, and a permanent magnet that fits inside the impeller (Fig.1). Two tests were conducted sequentially for INDUS pump prototype and CentriMag[®] pump under identical test conditions. The pumps were used in the mock loop along with the CentriMag[®] motor and controller, inlet and outlet pressure sensors, non-contact flow sensor and a screw clamp to control the flow rate in the loop (Fig 2). The mock loop was filled with 400±20 mL of a blood analogue Glycerol-Water solution at 37.0°C., adjusted to ~4.0 cP.

The RPM (500-5500) was adjusted with the CentriMag[®] controller. The flow rate was controlled using the screw clamp at the outlet of the pump, from the fully open condition (Max flow rate) to the fully closed condition (0 LPM) with an increment of 1.0 LPM. The non-contact flow probe displayed the flow rates on the controller. The inlet and outlet pressures were recorded for the corresponding flow rates using the WinDaq[®] data acquisition software.

Results: Pressure vs Flow Rate or H-Q curves were plotted for various RPMs (Fig.3). The INDUS pump H-Q curves were found to closely approximate the CentriMag[®], specifically for low RPMs (up to 3000). The INDUS pump could achieve a maximum pressure head as high as 763 mmHg at 5500 RPM.

Conclusion: The H-Q curves achieved for the initial prototype of INDUS pump meet the design criteria and user requirements as an LVAD (Between 2000-3000 RPM, 4.0-5.0 LPM, 100-120 mmHg) and an ECMO blood pump (Between 4000-5000 RPM, 5.0-6.0 LPM, 500-600 mmHg). This promising result serves as a key step towards the development of a low-cost indigenous blood pump for India. Ongoing work includes further CFD analysis, final development of the injection moulded pump and an indigenous Maglev motor.

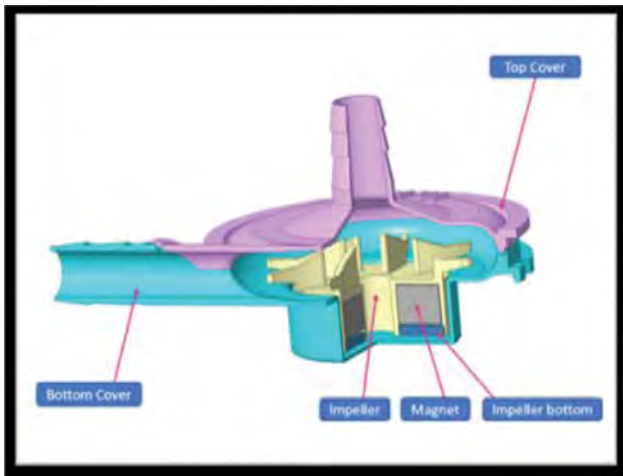


Figure 1. Components of INDUS.

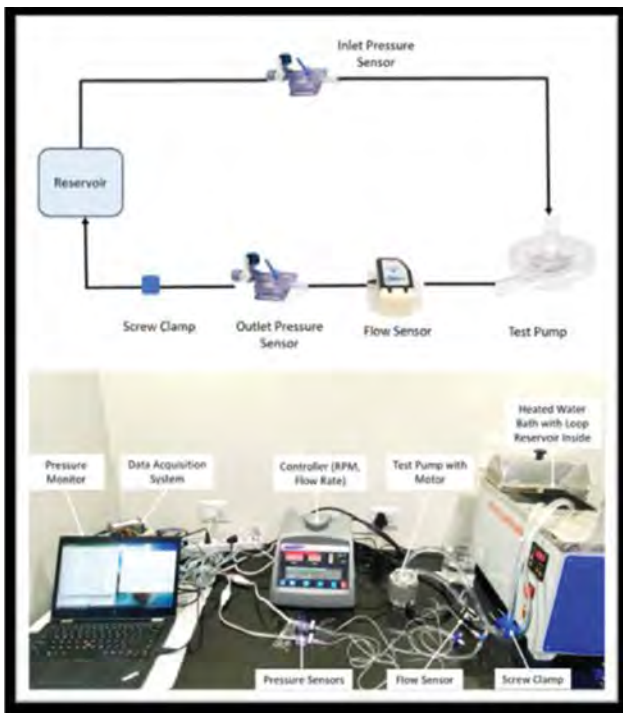


Figure 2. Mock Circulatory Loop for Hydrodynamic Test.

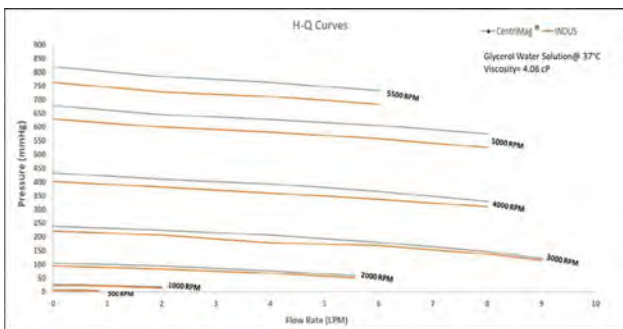


Figure 3. H-Q curves comparing INDUS Pump Prototype with CentriMag® Pump.

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Patient-Specific Soft Robotic Cardiac Simulator for Advanced Surgical Training

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Background: Cardiac simulators for surgical training have proven instrumental in honing surgeons' expertise, allowing them to perform surgical treatments in a safe, realistic, and controlled environment. Therefore, developing hemodynamically and anatomically realistic training platforms is essential for clinicians to devise tailored solutions for patients, enhance accuracy and efficacy, and minimize surgical risks. In this work, we developed a patient-specific beating heart simulator integrated into a mock circulatory system and actuated through soft robotic technology. Specifically, the use of soft robotic actuators enabled us to obtain an active ventricular contraction, producing physiological hemodynamics without using an external pulsatile pump.

Methods: A patient-specific right ventricle model was developed employing silicone injection molding technique. Starting from CT images of a patient, design solutions were implemented with CAD software, and silicone injection molds were 3D printed in PLA. A heat-soluble core in prosthetic animal gelatine was used to reproduce the internal heart cavity. Soft pneumatic artificial muscles (PAMs) that contract when pressurized with air were used to achieve active contraction of the ventricular model. Specifically, PneuNets and McKibben soft robots were developed and characterized in terms of contraction, force development, and operating pressure. A design study was conducted to incorporate them into the ventricle model, aiming to obtain circumferential and longitudinal contraction. Furthermore, the heart model was integrated into a dedicated cardiovascular mock-loop with mechanical support valves to reproduce the cardiac phases by analyzing the fluid dynamic parameters of interest.

Results: The patient-specific right ventricle model, obtained through silicone injection molding, accurately replicated heart anatomy. Using soft robotic actuators enabled active ventricular contraction, overcoming limitations of the paradoxical movement typical of passive heart simulators and preventing unnatural heart contractions. The incorporation of a cardiovascular mock-loop with mechanical support valves allowed for the faithful reproduction of cardiac phases, resulting in a realistic simulation of fluid dynamic parameters.

Conclusion: The developed cardiac simulator, using soft robotic technology and a dedicated cardiovascular mock-loop, is a valuable training tool for surgeons and exhibits potential uses in medical device testing and research. The ability to accurately replicate physiological conditions and fluid dynamics positions the simulator as a versatile tool to advance surgical training methodologies and cardiovascular research efforts.

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Validating a 3D biventricular heart model in a mock circulatory loop

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Background: Biventricular interactions occur during both systole and diastole via shared fibres, the interventricular septum, and the pericardium. While ventricular interdependence has been simulated in computer-based mock circulatory loops (MCLs), it has not yet been incorporated into a physical model of the human circulation. The purpose of this study was to test and validate a novel 3D printed biventricular heart model in a physical MCL.

Methods: A biventricular model with two silicon diaphragms with a shared interventricular septum was installed in an existing MCL to assess whether it could replicate a normal circulatory state, as well as left ventricular failure, right ventricular failure, and biventricular failure. This model was also assessed for ventricular interdependence by clamping systemic venous inflow in order to reduce right-heart volume and assess changes in left atrial pressure.

Results: The biventricular model successfully replicated normal and ventricular failure cardiac states (Table 1). The separate ventricle model did not demonstrate ventricular interdependence (Figure 1a) but the biventricular model demonstrated ventricular interdependence (Figure 1b), with ratio of LAP to RAP change of 0.47.

Conclusion: A biventricular model can functionally replicate a heart with ventricular interactions in a mock circulatory loop.

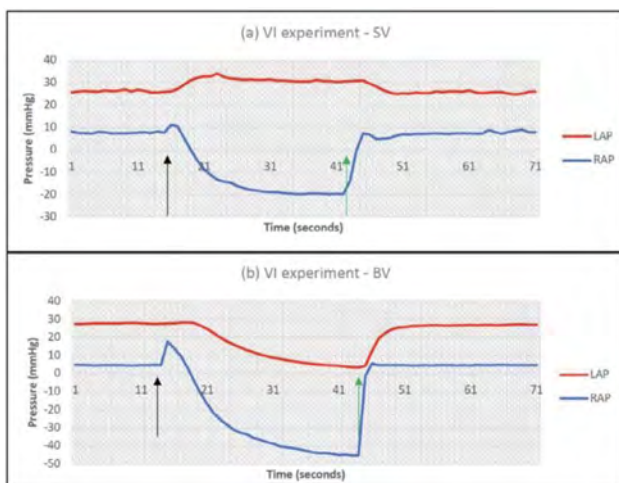


Figure 1. The black arrow indicates the point of the clamp being applied and green arrow indicates the point of unclamping. (a) Ventricular interdependence experiment performed in the separate ventricle model showing the change in LAP and RAP over time. (b) Ventricular interdependence experiment performed in the biventricular model showing the change in LAP and RAP over time. VI = Ventricular interdependence, SV = separate-ventricle model, BV = biventricular model, LAP = left atrial pressure, RAP = right atrial pressure.

Table 1. Reproduction of normal circulatory, left ventricular failure, right ventricular failure and biventricular failure states

State	mAoP (mmHg)	LAP (mmHg)	RAP (mmHg)	Flow (L/min)
Normal	81.0	14.4	8.9	3.04
LVF	67.4	27.7	8.5	1.36
RVF	62.1	4.2	30.2	1.54
BVF	57.1	28.5	28.4	1.51

LVF = left ventricular failure; RVF = right ventricular failure; BVF = biventricular failure mAoP = mean aortic pressure; LAP = left atrial pressure; RAP = right atrial pressure;

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New Challenge To HM3 With Lowering Anticoagulation Regimen: Long Term Follow up Single Center Experience

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Purpose

In this study we describe our data with regards to the anticoagulation regimen and examine the mid-term outcomes for VAD patients who received ASA/warfarin compared to those who received Warfarin alone. Methods: This is retrospective chart review of all LVAD patients who were implanted at our center. Informed consent was taken.

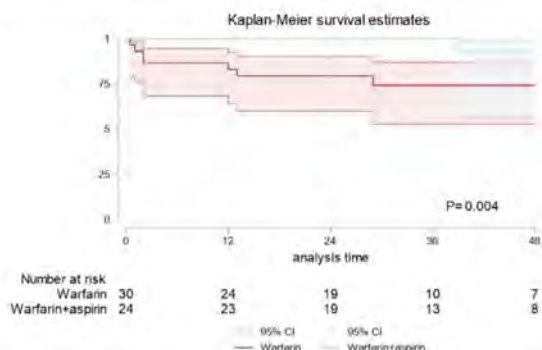
Results: 58 patients underwent HM3 implantation between Apr2016 till Nov 2023 with Median follow up of 40 months (13- 84). 4 were excluded as they were not under any sort of anticoagulation due to coagulopathy. of the remaining, 30 patients received warfarin alone and 24 received ASA/warfarin. There was no difference between groups regarding baseline characteristics. The ASA/Warfarin group had higher PVR (P= 0.046). Early post-op results (within 30 days) showed no differences in stroke (P= 0.36), bleeding (P= 0.73) (Tab2). The long-term outcome, GI bleeding occurred in 6 patients in the warfarin group compared to 2 in other group (P= 0.27). Device thrombosis occurred in 1 patient in the ASA/Warfarin group and none in the Warfarin group. Mortality occurred in 10 patients: 9 in the Warfarin group and 1 in other group (P= 0.004). Survival at 1 and last follow up, was 83% and 79% in the Warfarin group, and 100%, and 96% in other group.

Conclusion: Our observational study showed that there is no difference with regards to early post-operative outcomes for patients whether they received Warfarin alone or Aspirin and Warfarin after LVAD implantation. However, there was a long-term survival benefit for patient who received both Aspirin and Warfarin. Following up long term outcomes of The ARIES-HM3 Randomized Clinical Trial will clarify our hypothesis.

Table 2: Comparison of the operative and postoperative data between patients with assisted ventricular devices who received Warfarin vs. Warfarin and aspirin.

	Warfarin (n= 30)	Warfarin and aspirin (n= 24)	P-value
Stroke	4 (13.33%)	1 (4.17%)	0.367
Bleeding	5 (16.67%)	5 (20.83%)	0.736
Dialysis	6 (20%)	3 (12.50%)	0.715
Pneumonia	8 (26.67%)	10 (41.67%)	0.264
Driveline infection	6 (20%)	6 (25%)	0.748
Right ventricular dysfunction	1 (3.45%)	0	0.862
0	6 (20.69%)	4 (17.39%)	
I	15 (51.72%)	11 (47.83%)	
II	7 (24.14%)	8 (34.78%)	
III			
ALT (IU/L)	20.05 (15- 37)	28 (14.5- 37)	0.607
AST (IU/L)	41.7 (23- 76.2)	42 (25.5- 58.6)	0.866
INR	2.30± 0.41	2.29± 0.45	0.94

Figure 3: Kaplan-Meier curve for survival in patients with assisted ventricular devices on Warfarin or Warfarin and aspirin.



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Paracorporeal Ventricular Assist Device as Bridge to Transplant after Suspected SARS-CoV-2 Myocarditis in Child with Stage II Single Ventricle Palliation

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A 9.2kg 10 month old male with hypoplastic left heart syndrome (mitral and aortic stenosis) who had undergone a Norwood with Blalock-Taussig-Thomas shunt and atrial septectomy at 5 days old, a bidirectional Glenn at 3 months old, and aortic coarctation stenting at 5 months old, presented with 2 days of emesis and 1 day of lethargy and cyanosis in the setting of a sick sibling at home. Prior to presentation, he had normal right ventricular function and mild tricuspid regurgitation and was on aspirin, enalapril and furosemide. Examination revealed compensated cardiogenic shock and laboratory evaluation was remarkable for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and markedly elevated troponin and NT-proBNP levels. Electrocardiography showed sinus tachycardia with diffuse ST changes and echocardiography demonstrated severely depressed global right ventricular systolic function and severe tricuspid regurgitation without Glenn or aortic obstruction. The constellation of findings was consistent with SARS-CoV-2 myocarditis. He was transitioned to intravenous milrinone and furosemide and placed on high-flow nasal cannula and SARS-CoV-2 therapies.

With worsening troponin leak and diffuse ST changes and development of new runs of polymorphic ventricular tachycardia within 24 hours of admission, the patient was intubated and electively placed on central venoarterial extracorporeal membrane oxygenation (ECMO) without need for cardiopulmonary resuscitation. To optimize hemodynamics for decannulation, on day 6 of ECMO a cardiac catheterization was performed to balloon dilate the coarctation stent where there was mild angiographic narrowing without gradient, with good angiographic result. He separated from ECMO on day 7 with delayed sternal closure the day after, but inability to wean off dual inotropy and mechanical ventilation prompted CentriMag™ single ventricular assist device (SVAD) placement via common atrial and ascending neo-aortic cannulation 9 days after ECMO decannulation. With high pump fibrin burden despite bivalirudin anticoagulation and dual antiplatelet therapy, a bedside pump change to a 25mL Berlin Heart EXCOR® was performed 8 days later without complications. Serial assessments during his relatively stable SVAD course demonstrated no evidence of myocardial recovery.

Following intensive physical and nutritional rehabilitation, he underwent orthotopic heart transplantation with aortic arch reconstruction 7 months after his initial presentation. He had a right heart catheterization on post-transplant day 12 that demonstrated expected biventricular diastolic dysfunction and a moderate aortopulmonary collateral burden, and he was discharged home on oral medications and room air on post-transplant day 27. To our knowledge, this is the first reported case of suspected SARS-CoV-2 myocarditis in a child with stage II single ventricle palliation who was successfully bridged using a paracorporeal SVAD to heart transplantation.

P71

Cardiogenic Shock Algorithm Improves Patient Outcomes: Single Center Experience

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Background: Cardiogenic shock (CS) mortality remains high, around 50% nationwide.

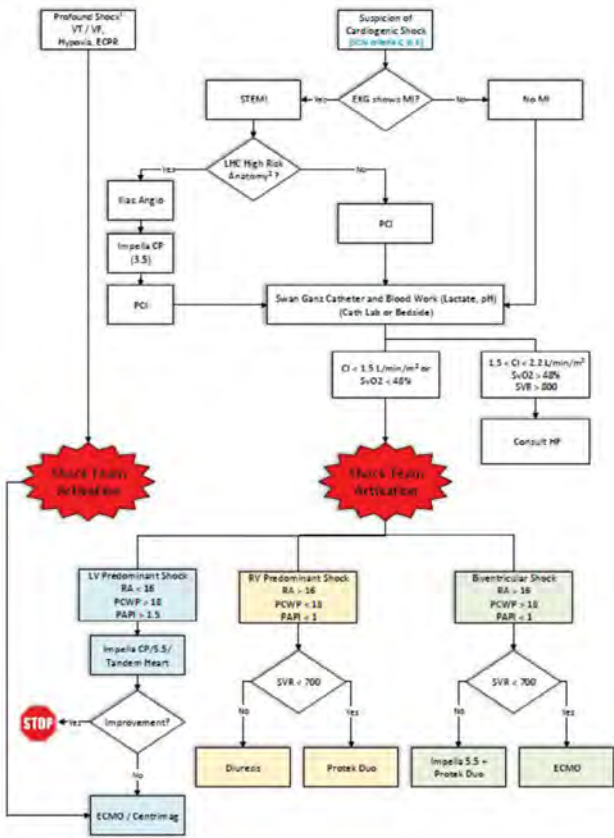
At Tampa General Hospital we identified the need to implement a structured program to improve CS mortality. As a result, multiple opportunities were identified in the care of patients with CS.

Methods: We conducted an in-depth evaluation to appropriately identify and risk stratify patients in CS. This led to establishing CS protocols as a guide to medical and mechanical circulatory support (MCS). The algorithm begins with suspicion of CS and designation of SCAI class/criteria. Cases are then separated into two main categories of CS causing pathophysiology: ST-elevation myocardial infarction (STEMI) vs no myocardial infarction (MI)/ heart failure (HF). If the need for percutaneous coronary intervention (PCI) has been ruled out, advanced hemodynamic monitoring is advised to gauge severity and drive urgency. At this point, a HF consult, or Shock Team Activation is indicated. The remainder of the protocol recommendations are MCS decision geared for use by the C-shock team.

Results: From January 1st-Dec 31st in 2022 there were 218 alerts for 128 individual patients. 2023 saw a rise to total 321 alerts for 189 individual patients. Surprisingly, the individual patient death rate of 69 remained the same for both years and the recovered percentage grew from 19% in 2022 to 24% in 2023. Transplanted patients also increased from 3.2% in 2022 to 4.3% in 2023. SCAI classes D and E were 46% and 19% in 2022 respectively. SCAI classes D and E rose to 49% and 24% in 2023 respectively, suggesting greater patient acuity from the previous year. MCS strategies were listed by disposition following a c-shock alert meeting. These numbers reflect the therapy chosen, guided by the protocol, not necessarily the therapy the patient received.

Conclusions: A structured CS program algorithm based on well-defined protocols leads to decreased mortality in CS patients. Classification of this patient population utilizing uniform SCAI class assignment and implementation a treatment algorithm was paramount in activating resources and MCS in a timely manner.

Cardiogenic Shock Protocol



Outcomes per alert	2022	2023
Total Alerts	218	321
Individual Patients	128	189
Death	69	69
Durable LVAD	8	7
Recovered	42	79
Transplanted	7	14
Other/ Unknown	2	20
SCAI Class per alert	2022 CS Alerts	2023 CS Alerts
A	0	0
B	2	2
C	44	69
D	101	158
E	42	78
Other/ Not Applicable	29	14

MCS Strategies per alert	2022 Usage	2023 Usage
VV ECMO	3	0
VA ECMO	61	63
BIVAD	13	8
RVAD/ Impella RP Flex	5	10
Impella CP	17	16
Impella 5.5	21	36
IABP	14	22
MCS de-escalation	11	57
Medical Management	65	99
Other/ Cancelled	8	10

P72

Evaluating N-terminal pro-brain natriuretic peptide as a Reliable Predictor for Contrast-Induced Nephropathy in Patients Undergoing Percutaneous Coronary Intervention: A Systematic Review and Diagnostic Accuracy Meta-Analysis

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Background: The prediction of Contrast-Induced Nephropathy (CIN) after percutaneous coronary intervention (PCI) is of significant medical concern, impacting the patient's overall prognosis. N-terminal pro-brain natriuretic peptide (NT-proBNP) has been suggested as a potential predictive biomarker. This study aimed to assess the diagnostic accuracy of NT-proBNP levels in predicting contrast-induced nephropathy in patients undergoing percutaneous coronary intervention.

Methods: We systematically searched databases such as PubMed, Embase, and Scopus until November 2023 for studies examining the diagnostic accuracy of NT-proBNP in predicting CIN in PCI patients. A univariate random-effects model was used for the meta-analysis, and statistical analyses were conducted with R software (version 4.0.3) using the mada package. This allowed us to pool sensitivity, specificity, estimates of false-positive rates, diagnostic odds ratios, and positive and negative Likelihood Ratios (LR). These outcomes are reported with a 95% Confidence Interval (CI).

Results: Our meta-analysis included 6 studies, with a combined patient total of 3873, among whom 236 developed contrast-induced nephropathies. There was considerable variability across studies owing to different NT-proBNP cut-off values and CIN definitions. The pooled sensitivity and specificity for NT-proBNP in predicting CIN were 76.4% (95% CI, 70-81.8%, I²=20.9%) and 70.7% (95% CI, 69.2-72.2%, I²=56.3%), respectively. The false-positive rate stood at 29.3% (95% CI, 27.8-30.8%). The positive likelihood ratio was 2.61 (95% CI, 2.38-2.86), the negative likelihood ratio was 0.33 (95% CI, 0.26-0.43), and the overall diagnostic odds ratio of 7.82 (95% CI, 5.59-10.92).

Conclusion: The study suggests that NT-proBNP could serve as a relatively accurate predictor of CIN in PCI patients. However, we identified a significant variation in the optimal cut-off values and timing of NT-proBNP measurement, which requires further investigation. These findings provide a robust foundation for subsequent research in CIN prevention in PCI patients and contribute towards the development of early preventative strategies.

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Conclusion: A proof of concept safer, reproducible alternative to sternal reentry is provided. We postulate that catastrophic hemorrhage at sternal reentry can be avoided with this technique and construct.

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Conclusion: CCB target L-type voltage gated calcium channels are located in the heart, peripheral vasculature, and pancreas. Overdose causes hemodynamic collapse. Rarely patients develop NCPE, the severity of which has been shown to require VV ECMO. Treatment is with calcium, high dose insulin, inotropes, vasopressors, and occasionally lipid emulsion, plasma exchange, and ECLS. Upon literature review, our case appears to be a novel presentation of CCB overdose that consisted of both hemodynamic collapse and NCPE. Recent studies have demonstrated algorithms for initiation of VA ECMO for cardiotoxicity. However, the combined NCPE and hemodynamic collapse made our clinical decision making more complicated, resulting in numerous ECMO configurations to adequately support both cardiac and respiratory failure.

P75

Refinement of an Algorithm Monitoring Transvalvular Micro-Axial Flow Pump Position

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Background: Placement monitoring of a transvalvular micro-axial flow pump can be challenging due to various environmental physiological factors and their effect on pump performance, especially in the setting of full hemodynamic support with minimal ventricular contraction. Increased specificity of placement monitoring algorithms in challenge cases can reduce both alarm burden and the need for additional echocardiography. The following describes an algorithm logic with refined parameters to optimize pump position detection leveraging clinical patient data logs.

Methods: Position detection data from patient cases (n=100+) and *in vitro* studies were pooled and categorized based on identified position and real pump position, revealing patterns about false positives. From this data set a novel algorithm was developed utilizing motor readings and physiological patient pressures to account for pump performance and clinical environmental factors such as respiration and external ventilation, full ventricular unloading, pump suction, and device interference, accommodating a range of heart rates. For algorithm validation unique patient cases (n=100+) covering a mean arterial pressure range of 26 – 150 mmHg with pulse pressures from 0 – 100 mmHg were evaluated with the predicate and novel algorithms. Algorithm outputs on the development data set were compared via confusion matrix, and algorithm performance on the validation data set was evaluated by empirical analysis.

Results: Based on the unique data set for algorithm validation, the refined algorithm demonstrated improved sensitivity and specificity compared with the predicate. With minimal clinical data available at the time, the predicate algorithm was developed via bench data. Overall, there was improvement in position detection accuracy across all pump positions at various physiological conditions, including reduction in false positives for aortic/ventricular malposition. There were no false negatives for any conditions in over 120+ days (total time) of validation data.

Conclusions: Algorithm refinement was enabled by constant collection of clinical performance data bolstering existing *in vitro* data. Continuous refinement of monitoring algorithms with the use of clinical data allows for improvement in position detection specificity via analysis and assessment of clinical edge cases.

P76

Reduced Left Ventricular Assist Device Utilization And Post-Transplant Survival After Donor Allocation Policy Change

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Background: We sought to estimate waitlist and post-transplant survival trends in patients supported on durable left ventricular assist devices in relation to the UNOS donor heart allocation policy revision.

Methods: Patients implanted with HeartMate 3 LVAD, HeartMate 2 LVAD, or HeartWare HVAD (LVAD) and listed for isolated heart transplantation between October 18, 2013, and June 16, 2023, were identified in the UNOS database and were stratified into pre- and post-policy revision (October 18, 2018) groups. Patients on temporary circulatory support, right ventricular assist device, total artificial heart, as well as simultaneous multiorgan transplants were excluded. Waitlist and post-transplant survival was analyzed and compared between these two groups.

Results: Overall, 7,664 patients were listed with LVAD (Pre: 4,144, Post: 3,520), and 7,253 patients underwent isolated heart transplant (Pre: 4,853, Post: 2,400). Policy revisions were associated with decrease in patients supported on LVADs (42.3% vs. 19.8%, p<0.01). For those listed with an LVAD, fewer patients eventually underwent transplantation (74% vs. 63.3%, p<0.01). Waitlist survival was comparable among patients supported on LVADs (p=0.7, Figure 1A). Following the policy change, patients supported with an LVAD at the time of transplant had a worse survival compared to prior to the policy change (p<0.01, Figure 1B).

Conclusion: Allocation policy revisions have resulted in decreased utilization of durable LVADs, and decreased rate of transplant off LVADs. After allocation policy changes, post-transplant survival worsened in patients supported on LVADs.

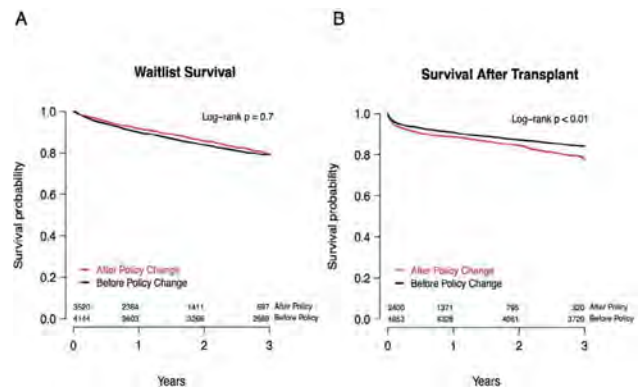


Figure 1. A Kaplan-Meier survival curves for all waitlisted LVAD patients, before and after the policy change. **B** Kaplan-Meier survival curves for all transplanted LVAD patients, before and after the policy change.

P77

Application of Impella 5.5 to Support Patients on Cardiogenic Shock

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Purpose: Temporary percutaneous transvalvular axial flow pumps continue to expand their role in cardiogenic shock (CS) as device strategic measures. The latest iteration of said devices withhold longer implantation durations without the risk of left ventricular complications, facilitated maneuverability, and higher dynamic cardiac flow profiles. The purpose of this study is to characterize the perioperative profile and outcomes of patients with CS under Impella 5.5 temporary mechanical circulatory support (TMCS).

Methods: A retrospective review of prospectively collected data was performed to identify CS patients receiving Impella 5.5 TMCS from January 2020 to December 2023. The cohort was separated into two groups: Those with ischemic cardiomyopathy (Group A) and those with non-ischemic cardiomyopathy (Group B). Upon cohort identification, the data was reviewed for general demographics and comorbidities, CS staging at TMCS. The assessment of outcomes focused on inotrope requirement at TMCS initiation, complications following TMCS, time on TMCS, device strategy course (e.g.: Expected recovery [ER], bridge to LVAD [DT], and bridge-to-transplant [BTT]), discharge disposition, follow-up time, survival rates following TMCS, and current status. Categorical data was determined in numbers and percentages, while continuous data was represented in averages and standard deviation. Fisher's exact tests were conducted to determine the level of association of categorical data, and t tests were performed to compare means between groups.

Results: Forty-two patients were identified for assessment. Table 1 summarizes all patient general demographics, clinical and surgical characteristics. Overall, the cohort was predominantly male (88%), with a mean age of 55.3 ± 14.4 years, and having non-ischemic cardiomyopathy (NICMP) as the most common etiology for CS (62%). The predominant strategy following TMCS was BTT in 29 patients (69%), including 9 in group A and 20 in group B (56% and 77%, respectively; $p=0.19$). Preoperative inotropes were required in most patients in both groups (69 and 73%; $p=1.0$). The most common outcome following TMCS was home healthcare discharge (38%), followed by expiration during index admission (31%) (for groups B and A, respectively). Although group B showed higher survival rates ($A=50\%$ versus $B=73\%$; $p=0.19$), no statistical significance was determined. This was similar to survival time following both TMCS and transplant in those undergoing BTT. Notably, time from transplant to discharge was significantly shorter in Group B ($p=0.02$) which presented a higher distribution of patients in advanced stages of CS.

Conclusions: The Impella 5.5 pump provides critical support for patients with varying degrees of CS. Based on this initial experience, this pump yields optimal outcomes as a device strategic approach in high-risk patients.

	TOTAL	Group A N = 16	Group B N = 26	P value ($\alpha=0.05$)
	Mean $\pm$ SD or N (%)	Mean $\pm$ SD or N (%)	Mean $\pm$ SD or N (%)	
Age (years)	55.3 ± 14.4	59.1 ± 12.5	53.9 ± 15.3	0.1874
Gender (M)	37 (88)	14 (88)	23 (88)	1.0
Etiology				
ICMP	16 (38)			
NICMP	26 (62)			
BMI (kg/m^2)	29.8 ± 7.0	29.6 ± 6.0	29.9 ± 7.7	0.895
Comorbidities				
HTN	18 (43)	7 (44)	11 (42)	1.0
T2DM	13 (31)	7 (44)	6 (23)	0.1868
CAD	17 (40)	12 (75)	5 (19)	0.0009
CVA	11 (26)	9 (56)	2 (8)	0.0009
AKI at TMCS	26 (62)	11 (69)	15 (58)	0.5298
CKD	20 (48)	9 (56)	11 (42)	0.5285
SCAI stage				
SCAI C	11 (26)	5 (31)	6 (23)	0.7203
SCAI D	18 (43)	7 (44)	11 (42)	1.0
SCAI E	13 (31)	4 (25)	9 (35)	0.7326
Required inotropic support	30 (71)	11 (69)	19 (73)	1.0
Required escalation/transition/additional support	16 (38)	7 (44)	9 (35)	0.7445
Type				
VA-ECMO	14 (33)	6 (38)	8 (31)	0.7418
VV-ECMO	1 (2)	0 (0)	1 (4)	1.0
IABP	1 (2)	1 (6)	0 (0)	0.3810
LOS (days)				
Total	43.9 ± 25.0	44.8 ± 27.6	43.4 ± 23.7	0.8027
Admission-to-TMCS	6.9 ± 11.6	9.0 ± 17.4	5.5 ± 7.7	0.3488
TMCS-to-discharge	37.0 ± 23.4	35.8 ± 21.0	37.9 ± 25.1	0.7915

	TOTAL	Group A N = 16	Group B N = 26	P value ($\alpha=0.05$)
	Mean $\pm$ SD or N (%)	Mean $\pm$ SD or N (%)	Mean $\pm$ SD or N (%)	
Time on Impella 5.5	19.9 ± 15.5	16.6 ± 14.5	20.5 ± 18.1	0.4337
Device strategy course				
ER	7 (17)	5 (31)	2 (8)	0.1798
Expired under support	8 (14)	2 (13)	6 (23)	1.0
BTT	29 (69)	9 (56)	20 (77)	0.1066
Simultaneous KT	3 (7)	0	3 (12)	0.2573
Complications				
Device related	17 (40)	6 (38)	11 (42)	1.0
Hemorrhagic/Thrombotic	4 (10)	1 (6)	3 (12)	
Mechanical	1 (2)	0	1 (4)	
Patient related	9 (21)	4 (25)	5 (19)	
Hemorrhagic/Thrombotic	5 (12)	2	3	
Other	4 (10)	1 (6)	3 (12)	
Infectious	4 (10)	1 (6)	3 (12)	
BTT course (days)				
TMCS-to-listing	10.3 ± 19.9	3.8 ± 8.0	13.1 ± 22.8	0.125
TMCS-to-transplantation	20.8 ± 22.2	10.7 ± 15.0	21.4 ± 25.1	0.808
Admission-to-transplant	29.7 ± 19.6	34.0 ± 27.1	27.8 ± 15.7	0.3521
Transplant-to-discharge	20.9 ± 10.5	28.1 ± 9.9	18.6 ± 10.1	0.0226
Discharge disposition				
Home	4 (10)	0 (0)	4 (16)	0.2799
Home healthcare	13 (31)	3 (18)	10 (38)	0.3033
Acute rehab	10 (24)	4 (25)	6 (23)	1.0
Skilled nursing facility	2 (5)	2 (12)	0 (0)	0.1294
Hospice	3 (8)	2 (13)	1 (4)	0.5470
Expired during index admission	10 (24)	5 (31)	5 (19)	0.4649
Status at latest follow-up				
Alive	27 (64)	8 (50)	19 (73)	0.1876
Deceased	15 (36)	8 (50)	7 (27)	
Survival (days)				
Post TMCS	433.8 ± 440.8	409.4 ± 463.0	448.8 ± 435.3	0.7824
Post transplant	514.8 ± 410.0	443.9 ± 393.0	545.7 ± 423.0	0.4417

ER: Expected recovery; BTT: Bridged to transplantation; KT: Kidney transplant.

P78

Outflow Cannula Complications in Continuous Flow Left Ventricular Assist Devices (CF-LVADs): A Unique Case of Pump-associated Hemolysis Related to Thrombofibrinous Exudate

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Background: Continuous flow left ventricular assist device (CF-LVAD) implantation is associated with improved survival, functional capacity, and quality of life. While the risk profile has improved, outflow cannula complications can occur.

Case: A 48-year-old male underwent CF-LVAD implantation (HeartMate II) for idiopathic dilated cardiomyopathy as a bridge to heart transplantation. Although chronically elevated, patient presented to the hospital with an acute rise in lactate dehydrogenase (LDH), peak concentration 1367 U/L, concerning for pump-associated hemolysis. He was normotensive, without signs of heart failure, flow alarms, or an excessive burden of PI events. CF-LVAD parameters were appropriate: flow 4.2-5.3 liters/minute, speed 9200 revolutions/minute, power 5.0-5.8 watts, and pulsatility index 4.2-6.5. Transesophageal echocardiography obtained during recent cardioversion showed well-positioned inflow cannula. Plasma free hemoglobin was normal and no other signs of hemolysis were identified. LDH isozymes confirmed a rheologic etiology to elevation (LDH I, II elevated at 39.5%, 41.5%. LDH III, IV, V decreased at 14.4%, 3.1%, 1.5%). Resting surface echocardiography showed adequate LV unloading without aortic valve opening, moderate residual mitral regurgitation, moderate aortic regurgitation, and neutral septal positioning. Chest CT did not reveal inflow or outflow tract obstruction/kinking. CT angiography was avoided to preserve renal function. Cardiac transplantation occurred 6 weeks after presentation. This demonstrated outflow cannula invagination secondary to significant thrombofibrinous debris (Figure 1), resulting in flow pathway disturbance and hemolytic findings in the serum. No rotor thrombus was identified.

Discussion: LDH surveillance after CF-LVAD implantation is performed for LVAD-associated hemolysis. Although considered a reliable marker of pump-associated hemolysis, inflow or outflow cannula obstruction, dehydration or underfilled LV with increased inlet velocities, stenotic or regurgitant native or prosthetic valves with high jet velocities, outflow cannula pathologies, and transfusion associated immune and nonimmune-mediated hemolysis must also be considered. Here, absence of pump involvement was suggested by lack of new LV failure, device parameter changes, or alarms suggestive of pump failure. Typically, CT angiography is obtained to identify luminal thrombus or extrinsic compression of the outflow cannula, but contrast was avoided here. Thrombofibrinous exudate-mediated compression should be considered for elevated LDH, particularly in the proximal outflow cannula near the bend relief in patients with unmodified HeartMate bend reliefs.

Conclusion: This case highlights the differential diagnosis of elevated LDH in LVAD supported patients and the modest abnormalities on standard testing that create a challenge in diagnosis of extrinsic compression of the proximal outflow graft due to thrombofibrinous exudative material.

P79

Surfing the Dangerous Tide: A Tale of Left Main Chronic Total Occlusion Revascularization

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Background: Chronic total occlusion (CTO) of the left main (LM) coronary artery is rare and carries the worst prognosis of any coronary lesion due to the extensive myocardium that is supplied by this vessel. Percutaneous CTO recanalization is the “last resort” for patients who are not candidates for coronary artery bypass. The antegrade approach has limited efficacy and the retrograde approach using collateral channels for recanalization has been groundbreaking for patients who fail the antegrade approach. Using septal collateral channels for the retrograde technique is the safest option because it is less tortuous and allows a shorter route to the recipient vessel. Faintly visible septal channels can be crossed by the “surfing” technique which does not utilize contrast injection. While “septal surfing” is often resorted as a last option when performing a CTO recanalization, there are many risks including cardiac tamponade, myocardial hematoma, or infarction.

Case Information: The patient was a 72-year-old female with a past medical history of left main coronary artery CTO, right coronary artery collaterals, ischemic cardiomyopathy with an ejection fraction of 10%, and viability on MRI except for a small apical aneurysm. After discussion with the heart team, Impella-assisted LM CTO revascularization was planned. During the PCI, engaging the RCA donor vessel lead to ostial dissection needing direct stenting. Antegrade wire escalation failed after engaging the left system. A retrograde approach was attempted via “septal surfing” of the posterior septal perforators. Using the reverse CART technique, the PCI was successful for the left main trunk into the mid-LAD artery. Post PCI, the patient became non-pulsatile with Impella and developed ventricular fibrillation requiring defibrillation and CPR. Antegrade angiography showed persistent extravasation from the diagonal branches with effusion and collapse of the right ventricle on transthoracic echocardiogram. Covered stents placed in the LAD sealed the flow to the small diagonal branches which resolved the bleeding. Retrograde injections via RCA did not reveal persistent bleeding. The shock team was activated. Patient remained on Impella with worsening shock needing emergent bedside pericardiocentesis and VA ECMO initiation with ECPella configuration. The ICU course was complicated by a small subdural hemorrhage but she was eventually weaned and decannulated four days post-op. The impella was removed six days post-op and the patient was extubated seven days post-op with improvement in her clinical status. The patient was discharged to inpatient rehabilitation on day fifteen.

Conclusion: The retrograde technique can improve success rates for complicated left main CTO PCI but septal surfing of collaterals involves many risks. This case of a cardiac tamponade SCAI Stage E(A) shock post-PCI highlights both risks and rescue algorithms utilizing mechanical circulatory support and a multidisciplinary approach.

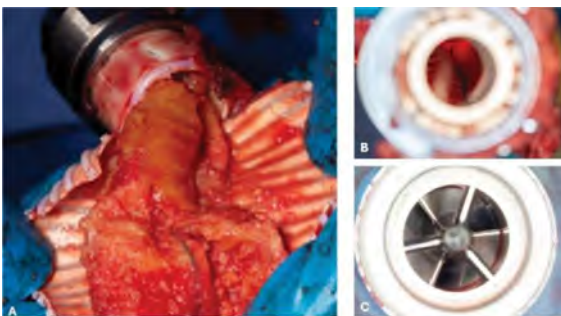


Figure 1: Explanted CF-LVAD outflow cannula disruption by thrombofibrinous exudative debris (A). Internal view of disrupted/invaginated outflow cannula (B). Pump rotor without signs of thrombus (C).

P80

Feasibility Of Using Ex-Vivo Porcine Heart To Simulate Closer To Natural Blood Flow Properties For Hemodynamic Studies

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Purpose: Most hemodynamic studies use pulse duplicators for simulation of blood flow. The pulsatile flow is generated by conversion of continuous flows to pulsatile flow by activation of valves that stimulate the cardiac valves. Additional flow properties such as Windkessel effect are achieved by adding other components to mimic the native cardiovascular system. The purpose of this study was to determine the feasibility of using an ex vivo heart to simulate closer to natural pulsatile flow properties for hemodynamic studies.

Methods: A fresh porcine heart is used to simulate the blood flow of either left, right or biventricular chambers, depending on the requirements. The heart is cannulated for the desired inflow and outflow chambers and connected to the study circuit. An appropriate size latex or silicon balloon is connected to a tube and the balloon is inserted into the ventricular chamber while the tube is externalized through the free wall of the ventricular chamber and secured with a purse strings. The balloon/s, connected to a custom-made air pump or alternatively to an intra-aortic balloon pump console, inflate and deflate in a desired frequency that represent the heart rate. Repetitive Inflation and deflation of the balloon inside the ventricular chamber ejects the fluid out of the chamber through the valve, similar to the blood flow during systole. The inflow of fluid into the ventricular chamber is provided by a continuous flow pump or by immersion of the heart under the fluid level. The fluid used for this study is a mixture of appropriately diluted Glycerin that has similar viscosity properties to those of blood. The physical properties of this simulator were assessed using flow meter and pressure transducer at the outflow point.

Results: This simulator was tested for modeling and simulation of blood flow in 3 different configurations, right ventricle only, left ventricle only and biventricular.

The physical properties of the ventricular muscle in the porcine heart (ex-vivo) and the elasticity of the balloon, created a flow profile which were very similar to those of seen with native circulation.

Summary: This high-fidelity simulator achieves a closer to natural blood flow properties to be used in hemodynamic studies. Using an ex-vivo heart to eject with by inflation of a balloon inside the chamber, is probably the closest condition to mimic native circulation after in-vivo condition. This simulator is low cost, easy to reconstruct and functions as an optimal cardiac simulator to be used instead of a laboratory animal.

P81

"Inventor, Investor, Surgeon": An Innovative Experiential Biomedical Device Design Role-Play Lab for Medical Students

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Background: Experiential educational activities are highly conducive to learning and retention because they provide extraordinary opportunities for application of knowledge in a realistic environment that is fun, interactive, engaging, low-pressure, voluntary, and not-graded. We developed an innovative mechanical circulatory support (MCS) lab called "Inventor, Investor, Surgeon" (IIS) designed for medical students as a vehicle for learning biomedical device design and entrepreneurial concepts through role-play.

Methods: We designed our IIS lab (1.5hrs) to be engaging, interactive, and presented in multiple modalities to encompass auditory, visual, and tactile forms of learning. Students were first provided a review of cardiovascular anatomy/function, heart failure (HF) pathophysiology, and a discussion of MCS therapy for HF. They next got to hold and interact with various MCS devices (ex. Abiomed AbioCor and Impella 2.5, Thoratec XVE, SynCardia TAH, Medtronic HVAD, Abbott HMII and HM3). They were then split into teams of 3 and each assumed one role: The Inventor (props included bowties, beakers) had to select an MCS device, articulate their rationale, and make a convincing elevator pitch to the Investor; The Investor (toy money and sportscars) had to evaluate whether to fund and champion the device and then convince the Surgeon to adopt its use; The Surgeon (surgical caps, stethoscopes) had to weigh device efficacy, clinical applications, and assess risk-benefits for their patient. Each IIS team then had to present and convince the other IIS teams that their device was superior. Students completed an anonymous evaluation (1-poor to 5-excellent) and provided written comments on their favorite and least-favorite aspects.

Results: Five labs have been held with 40 1st and 2nd year medical students participating. Students were interactive, had fun wearing/using the props for their respective roles, and engaged in highly animated discussions defending the device they chose, critiquing the others, and considering alternate viewpoints. Evaluations were extremely positive: students reported it was a useful educational experience (mean 5.0±0), they increased their knowledge and skills (mean 5.0±0), and the lab should be repeated in the future (mean 5.0±0). Key takeaways from their written responses included enjoying the passionate banter, dressing up, and having fun, and this was regardless of background or medical specialty interest.

Conclusion: Our innovative IIS lab confers enriching and well-received educational benefits reported by the students. In contrast to lecture-discussion or show-and-tell, role-play is a highly effective, interactive, and engaging educational tool. We demonstrated feasibility of our IIS lab to integrate MCS device design and entrepreneurial skills, concepts not emphasized in medical school curricula, into applied clinical critical thinking in a low-cost reproducible program through fun hands-on experiential role-play.



P82

Initial In Vivo Evaluation of a Novel Durable Veno-Venous Extracorporeal Membrane Oxygenation Cannula

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Background: For over 15 million patients with COPD and end-stage lung disease in the United States, a lung transplant is the only definitive treatment option. Transplantation is limited due to organ availability. Extracorporeal membrane oxygenation (ECMO) can be used as a bridge to transplant but is currently lacking in its ability to support long-term respiratory support due to constraints in durability. Our group has previously demonstrated our novel and durable VV ECMO cannula with an excellent pressure-flow profile compared to commercially available dual-lumen cannula. Here we expand our previous work by describing our in vivo large animal ovine studies in which we have implanted our device.

Methods: Our novel VV ECMO cannula was implanted via either a median sternotomy incision (n=1) or via a right thoracotomy incision (n=4) into healthy sheep. Surgical attachment to the heart was achieved via the right atrium with the cannula drainage tip in the superior vena cava and the reinfusion port directed towards the tricuspid valve. A Rotaflow blood pump and MC3 Nautilus Oxygenator were utilized for our circuit, which was set to obtain 2LPM flow and 1LPM sweep. Studies were run for at least a total of 6 hours on consistent flow.

Results: Through a series of initial in vivo studies, our novel cannula was successfully attached via the right atrium. Average flow consistent over 6 hours was 2LPM, average minimum flow was 1LPM and the highest flow achieved was 5LPM. Hemolysis measured as a function of plasma-free hemoglobin, was on average under 10mg/dL.

Conclusion: Our novel dual-lumen cannula has demonstrated promising utility in preliminary in vivo large animal ovine studies. In the future, we hope our cannula will be used by patients requiring durable mechanical circulatory support, offering ease of use and comfort over the standard approach.

P83

Outcomes in Cardiac Amyloidosis Patients

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Background: We sought to compare long term outcomes in patients with cardiac amyloidosis (CA) compared with those with non-ischemic cardiomyopathy (NICM) from a large healthcare system database.

Methods: CA or NICM patients were identified from SSM Healthcare System's data warehouse using ICD codes. Inclusion criteria included at least 6 months of follow up. Outcomes studied were heart failure admissions (HFA), ventricular tachyarrhythmias (VTA) and pacemaker (PM) placement. Multivariate Logistic analysis and Kaplan-Meier survival curves were constructed.

Results: We identified 237 patients with CA and 16,943 with NICM. CA patients were older (73.4±11.7 vs 64.4±14.6) and included more females (51.1 v.s 43.4%). 199 (84%) had Light chain (AL) amyloidosis. CA patient had higher incidence of HTN (78.9 vs. 68.6%), CAD (47.7 vs. 32.3%), CKD (32.1 vs. 24%). Mean follow was 48.1±33.1 months. CA patients had higher incidence of third degree (4.7 vs 2.4% p=0.02) and complete heart block (5.5 vs. 2.9%, p=0.02). There was no significant difference between groups in the rate of VTA or PM implantation. After adjusting for demographics and relevant comorbidities, CA patients had higher odds for HFA (1.55 (1.19-2.03); 95% CI).

Conclusions: In this retrospective study from a large healthcare system database, compared to NICM, CA patients had a significantly higher rate of HFA and high-grade heart block.

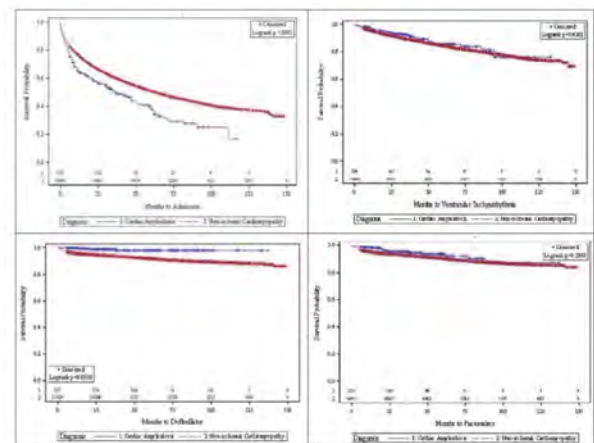


Figure: Kaplan-Meier curves for heart failure admissions (top left), ventricular tachyarrhythmias (top right), defibrillator (bottom left), and pacemaker implantation (bottom right)

P84

“Digital Dance”: Wearable Sensors and Signatures for Quantitative Monitoring of Human Motion for Dance Movement Therapy (DMT)

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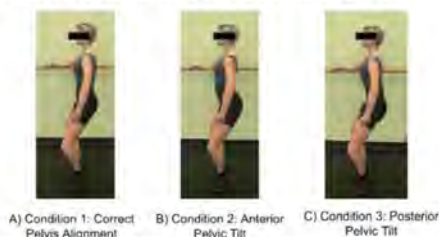
Background: Dance is a fine art, consisting of artistic and athletic body movements. Training exercises promote muscle building, flexibility and enhanced longevity as well as psychological uplift, all factors beneficial to health. To be effective, dance movements must be performed healthily and correctly with exacting body and limb movements. Classical ballet is a foundational style of dance developing basic body mechanics, technique and skills for dancers that are necessary for success in many styles of dance. The most foundational exercise is the demi plie which is performed as the first exercise of a classical ballet class and establishes a dancer's technical foundation. Here we evaluated the use of wearable stretchable electronic motion sensors (Biostamp) to track and define motion signatures associated with the tibialis anterior and sacrum during a demi plie. We hypothesized BioStamp technology would accurately track the movements of the demi plie, and that deviations in motion signatures are identifiable between dancers performing correct vs. incorrect demi plies as well as between collegiate level dancers and non-dancers.

Methods: BioStamps were placed on the left tibialis anterior and sacrum of seven injury-free, collegiate-level dancers as they participated in the three following conditions: (1) correct demi pliés, (2) incorrect demi pliés with an anterior pelvic tilt, and (3) incorrect demi pliés with a posterior pelvic tilt. Then, BioStamps were placed on six subjects with no previous dance experience as they performed Condition 1 after brief instruction. For all conditions, acceleration and gyroscope data was collected in the X, Y, and Z axes.

Results: The minimum amplitude values of the angular velocity about the X-axis of the sacrum, corresponding to anterior and posterior tilt, showed a significant difference between Conditions 1 and 2 ($p=0.0038$) and Conditions 1 and 3 ($p=0.0499$) within the “Dancer” group and between the Dancer and “Non-dancer” groups ($p=0.0374$). In addition, no statistically significant difference was found between the depth of plié (Z-axis acceleration of the tibialis anterior) across Conditions 1-3 in the Dancer group and in Condition 1 of the Non-dancer group [$F(3, 23) = 1.0878$, $p = 0.3741$]. No consistent patterns were found regarding medial and lateral motion of the tibialis anterior in both the Dancer and Non-dancer groups.

Conclusion: Wearable stretchable electronic motion sensors can accurately detect and quantify motions of the tibialis anterior and sacrum associated with the demi plie. Differences between correct and incorrect demi pliés as well as the difference between demi pliés of experienced dancers compared to that of subjects with no dance experience could be detected. Our results can be applied to detect unhealthy habits in dance that may lead to injuries, for early intervention for injury prevention. Future studies on DMT may also be supplemented by this digital wearable motion tracking technology.

Figure 1: Pelvic Orientation for Conditions 1-3



(A) The correct placement and technique at the bottom of classical demi plie. The dancer's pelvis is perpendicular to the floor with a completely upright torso and correct knee tracking adapted to the dancer's degree of turn out. (B) A demi plie with incorrect technique. The dancer's pelvis is tilted anteriorly which is classically incorrect. (C) A demi plie with incorrect technique. The dancer's pelvis is tilted posteriorly which is classically incorrect.

P85

Using Motion Capture to Enhance Patient Discharge: A Step Toward Quantitation and Standardization

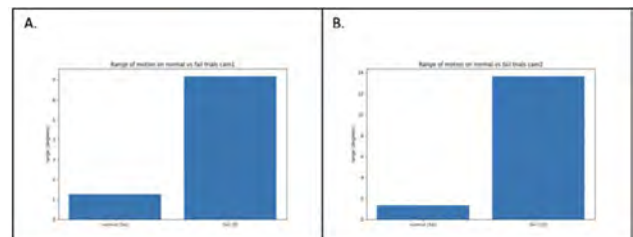
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Background: Hospitalization for chronic disease leads to significant debilitation of patients, including but not limited to loss of muscle mass and alterations in ability to ambulate and conduct daily tasks. Critical today is the assessment of the mobility status of patients prior to hospital discharge as incapacity requires admission to rehabilitation or step down facilities. To date, patient mobility exams are largely qualitative and often without standardization. Our group has developed a range of quantitative motion tests. We hypothesized that digital image analysis of defined motion exercises would allow for quantitative determination of regional and overall mobility, providing crucial data for discharge assessment.

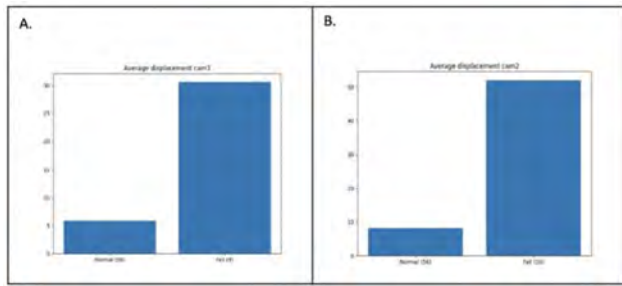
Methods: Thirteen healthy volunteer subjects (6M:7F, ages 15-22) placed green and pink stickers on defined body locations corresponding to specific mobility assessment motion routines. They were then asked to perform a series of exercises five times. These exercises were intended to replicate everyday motions including sitting up in bed, walking forward, and standing still. Participants were then asked to mimic a failed movement (ie. inability to sit up in bed, limping when walking, and wavering when standing) three times. All video recordings were taken from both the lateral and frontal view using a phone camera and tripod. Recordings were then uploaded and analyzed through MOCA, a motion analysis system that tracks the location of the colored stickers. The position of these markers over time was graphed and the velocity and acceleration were extrapolated. Endpoint variables like range of motion, displacement, and continuity of motion (smoothness) were analyzed.

Results: Range of motion was successfully measured (Figure 1), and differences in end point variables were present between regular trials and stimulated failures (Figure 2 and Figure 3). Our overall exam process from setting up, recording participants, and analyzing data, took on average 1.5 hours, significantly shorter than the 4.93 hours on average it takes for patients to complete the current discharge process.

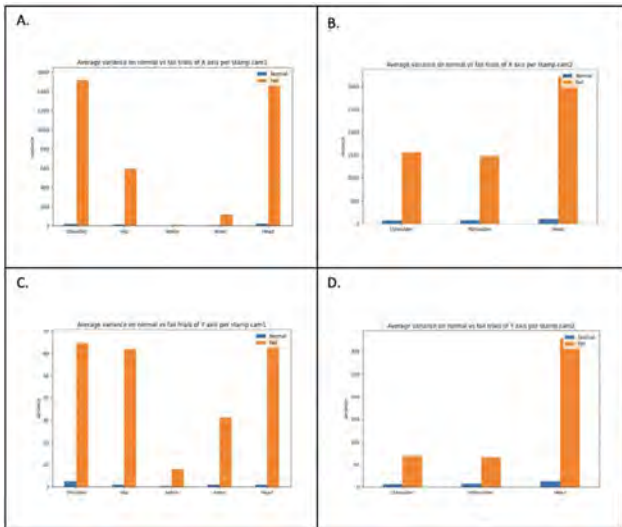
Conclusion: A patient discharge exam using motion tracking technology and simple, affordable materials (phone with camera, stickers, and a tripod) that can be administered by any healthcare professional could be used to differentiate range of motions between healthy and unhealthy patients, while also decreasing the time spent and demand for therapists. As we continue this study, administering this exam to hospital patients, we will also explore the potential of this evaluation to decrease unplanned hospital readmissions.



(A) Lateral View, (B) Frontal View.



(A) Lateral View, (B) Frontal View.



(A) Lateral View X, (B) Frontal View X, (C) Lateral View Y, (D) Frontal View Y

P86

Impella 5.5 as a Bridge to Recovery, Durable Mechanical Circulatory Support, or Heart Transplant: Outcomes and Hemodynamic Effects

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Purpose: Acute mechanical circulatory support is used to support the failing heart as a bridge to either recovery, durable mechanical circulatory support, or heart transplant. The Impella 5.5 is an axial-flow left ventricular assist device that is surgically implanted through the axillary artery and sits across the aortic valve providing up to 5.5 liters per minute of flow. Here we report the incidence of successful bridge compared with mortality and hemodynamic trends of 137 consecutive patients supported with Impella 5.5.

Methods: We conducted a single center observational study including all consecutive patients with advanced heart failure or cardiogenic shock supported with the Impella 5.5 from April 1st, 2021 through October 31st, 2023. Patients were included regardless of indication for mechanical support including upgrades from intra-aortic balloon pump counterpulsation or other percutaneous LVAD to Impella 5.5 as well as weaning from veno-arterial extracorporeal membrane oxygenation with or without secondary device for left ventricular unloading. Our primary outcome was a composite of recovery, durable left ventricular assist device placement, or heart transplant compared with all-cause mortality over 90 days using incident rate ratios and Kaplan-Meier curves. Hemodynamic and echocardiographic trends were recorded prior to Impella 5.5, on ICU arrival after placement, on day 2, day 7, and day 14. Repeated measures ANOVA and chi square test were used. Statistical analyses were performed using R (version 4.2.1).

Results: Patients were predominantly male (85.4%), middle-aged (mean age 54.3±12.6 years), and overweight (mean body mass index 28.4±5.9 kg/m²). Notable comorbidities included hypertension (65.7%), diabetes mellitus (52.6%), chronic kidney disease (17.5%), atrial fibrillation (43.8%), ventricular arrhythmias (44.5%), and tobacco use disorder (45.3%). The population included non-ischemic (53.3%) and ischemic (33.6%) predominant cardiomyopathies. INTERMACS scores were 1 (30.7%), 2 (63.5%), 3 (1.5%), 4 (2.2%). SCAI stages were E (27.0%), D (59.1%), C (11.7%). Figure A depicts Kaplan-Meier curves for the primary outcome and Figure B the incident rate ratios. Impella 5.5 did not appear to achieve left ventricular unloading as mitral regurgitation initially improved after Impella 5.5 placement, but worsened by day 14 (Figure C). Right ventricular-pulmonary artery interaction improved after Impella 5.5 placement with decreased pulmonary end arterial elastance (p<0.001) and increased pulmonary arterial compliance (p=0.025).

Conclusion: The Impella 5.5 provided effective support for end organ perfusion in this severely ill population evidenced by a higher rate of successful bridge to recovery, heart transplant, or durable mechanical circulatory support than mortality at 90 days. The hemodynamic and echocardiographic trends suggest that right ventricular-pulmonary arterial coupling improved, but effective left ventricular unloading was not achieved.

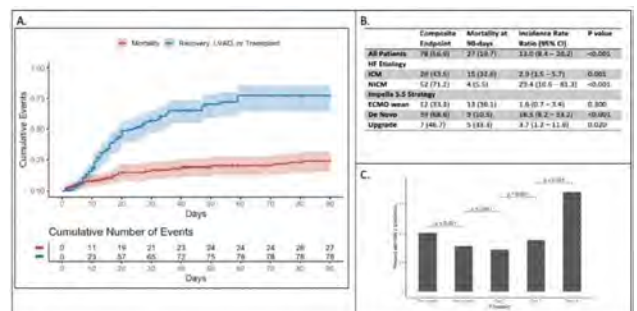


Figure 1.

P87

Mode Of Revascularization In Acute Coronary Syndrome In Patients Supported With MCS

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Purpose: Acute coronary syndrome (ACS) with cardiogenic shock(CS) is associated with a high mortality rate. With increased focus on acute unloading in addition to early revascularization, we sought to study the outcomes of various revascularization and MCS strategies.

Methods: We retrospectively reviewed the last 150 CS patients cared for at our tertiary care center; 79 patients underwent a revascularization procedure for ACS with MCS. Index devices: 5 IABP, 5 Impella 5.5 (5.5), 63 Impella CP (CP), 2 Bipella, and 4 Impella CP/ VA ECMO. Revascularization by CABG occurred in 11 patients and HRPPI in 68 patients.

Results: In the CABG group, 6 patients had CP, 1 Bipella, 1 IABP, and all but 2 of the CP patients were upgraded to the 5.5,. Three patients received the 5.5 as their index device in during surgery and 3 of the 5.5 patients also required VA ECMO. Only 1 patient did not receive LAD or LM revascularization. Mean time on support was 9.4 days. In the HRPPI group 29 patients were revascularized with index device (28 CP, 1 5.5) and 39 patients received device upgrade from index device. Prior to upgrade, 27 patients received full revascularization and 29 patients received LAD PCI as part of index procedure. The remaining 12 had culprit vessel revascularization followed by upgrade of device and then full revascularization. 12/27 (44%) patients died in the full revascularization prior to the upgrade group while 4/12(33%) patients died in the staged group. Mean time on support for the no upgrade group was 2.6 days vs 9.6 days in the upgrade group.

Conclusion: While survival to discharge was similar, full revascularization by CABG seems to be associated with better survival and improvement in EF, though tends to be best in a less sick population. When revascularization by PCI, full revascularization with optimal MCS seems to be more beneficial than acute PCI without adequate support. While this study is limited by a single center experience and small number of patients, further investigation into MCS strategies during revascularization would be beneficial.

P88

Applications Of The Impella Rp Flex: Single Center Experience:

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Purpose: Right ventricular dysfunction (RVD) is associated with increased morbidity and mortality in various cardiac syndromes. Early RV mechanical support can mitigate complications related to RVD, however options were typically cumbersome and extracorporeal, or required groin cannulation which limited rehabilitation of these patients. The Impella RP flex (RP flex; Abiomed, Davaers, MA) has provided an intracorporeal option that enables ambulation and rehabilitation of these complex patients.

Methods: Consecutive cases at our center using the Impella RP flex were evaluated for hemodynamics and quality measures.

Results: Eight patients received the RP flex: 1 for RV prophylaxis in mitral surgery, 1 for AMI shock, 3 peri-durable VAD RVD, 1 for post cardiectomy shock following weaning from ECMO, 1 Bi-Impella support post CABG and 1 CMP/CGS with BiV failure. Three out of the 8 patients had reduced EF requiring concomitant LV support (Heartmate 3, Abbott, Chicago IL) and 4/8 had pre-existing group 2 pulmonary hypertension with mean mPAP 43mmHg. Mean PAPI at baseline 1.45, mean PAP for all patients 37mmHg. Mean age was 63.4 years and 4 patients were female. 6/8 patients were able to participate in physical therapy within the first week post op and out of bed to chair 2.7days. None of the patients required renal replacement therapy during device support but 1 patient received renal replacement therapy 3 weeks post explant for fluid management. Only 1 patient had prolonged intubation d/t pneumonia. Mean days on RP flex support was 4.8 days (1-8 days). None of the patient's required longstanding inotropes and 4/8 patients required sildenafil at discharge, and 2/8 required sildenafil at 30 days post discharge. Six patients were successfully discharged with mean postoperative length of stay(LOS) 21.7 days, 13 day (8-16 days) mean LOS for patients with prophylactic RP flex and mean LOS for RV rescue patients of 22.5 days (8 -53 days). One patient expired (BIV failure CGS) while 1 patient remains hospitalized.

Conclusion: The RP flex is an intracorporeal RV assist device that allows for RV unloading in those patients who require short term RV support. It is best used early or in a prophylactic setting, allowing for stable hemodynamics in cases that would otherwise require high dose pressors and prolonged ICU care. Appropriate use of the RP flex offers patients who otherwise be too high risk a chance for recovery

Table 1.

	Initial Lactate	Survive to Explant	Survive to DC	EF Baseline	EF Explant	EF DC	EF 3-6mo
All	4.4	77.2% (61/79)	63.3% (50/79)	29.5%	31.9%	33.5%	41.2%
Re vasc CABG	4	81.2% (9/11)	72.7% (8/11)	34%	29.3%	40%	50%
PCI (ALL)	4.1	76.4% (52/68)	61.8% (42/68)	28.6%	32.4%	31.6%	38.9%
PCI No Up grade	3.5	79% (23/29)	65.5% (19/29)	26.8%	30%	34%	37.7%
PCI Up grade	5.1	74% (29/39)	59% (23/39)	24.3%	32.8%	30.4%	40%

P89

RostockTestCase - Open Access Geometry and High-Fidelity CFD Simulations of a Ventricular Assist Device

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Background: Numerical flow simulations and in-silico studies play a crucial role in the development and optimization of ventricular assist devices (VADs). They help evaluate the pump performance, stress fields, and make statements about hemocompatibility. The flow in a ventricular assist device is rather complex with turbulent flow characteristics and secondary flow structures. Therefore, flow validation of VAD simulations is important to ensure that the applied flow solver, the computational grid, and the simulation setup can represent the real VAD flow. Regarding that, the research group "Rotary Blood Pumps" at the University of Rostock provides a freely available test case of an axial ventricular assist devices on which interested researchers can test their simulation setup and compare their results with the results of a validated, high-fidelity large-eddy simulation of the VAD.

Methods: The test case is available at: <https://unibox.uni-rostock.de/getlink/fi8AE4mYS4kxu8ZY51oxDh/>
A documentation of the test case can be found at: <https://kbwiki.ercofac.org/w/index.php/AC7-03>

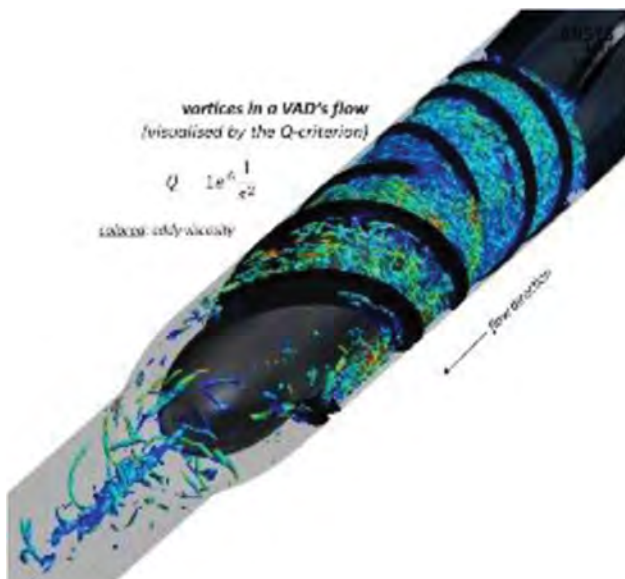
The test case can also be accessed through the QR code in the figure below.

Results: At these links, the full 3D geometry of the VAD can be found, along with detailed information about grid generation, simulation setup, and experimental validation. The validated, high-fidelity large-eddy simulation results showcase pump characteristics and stress fields, allowing for a direct comparison with a state-of-the-art Reynolds-averaged Navier-Stokes simulation in the documentation. Additionally, we have published blood damage prediction results at different operation conditions of the VAD.

Conclusions: The test case provides simulation engineers in the field of cardiac support with a validation opportunity for their numerical methods. Moreover, the well-documented simulation methodology within the test case offers researchers a comprehensive overview, facilitating the execution of high-quality Computational Fluid Dynamics studies in rotary blood pumps.



QR code to test case.



Instantaneous vortical structures computed by LES in the axial VAD. Visualised with the Q-criterion.

P90

Bronchial Stent Placement Under VV-ECMO For Severe Stenosis: A Case Report

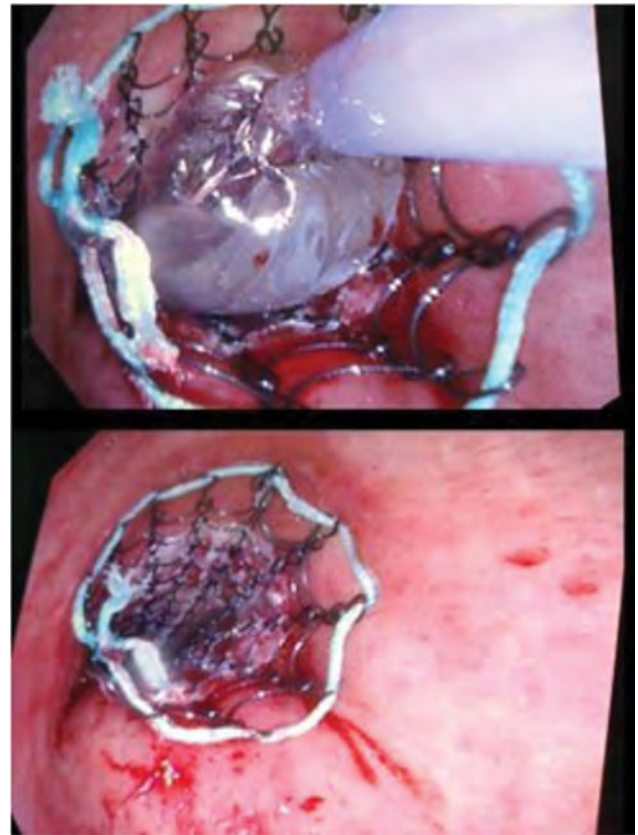
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Background: To report a case of bronchial stent placement under veno-venous extracorporeal membrane oxygenation (VV-ECMO) for a patient with severe stenosis of the left main bronchus due to lung cancer.

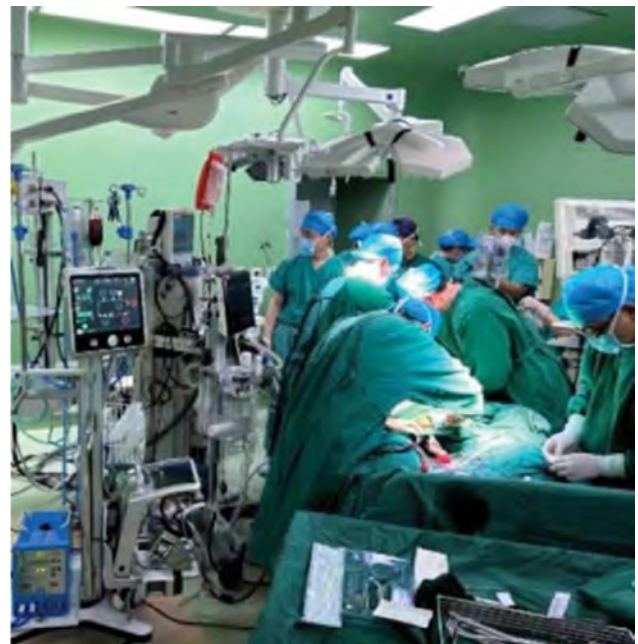
Methods: A 58-year-old male patient with lung squamous cell carcinoma and sarcomatoid carcinoma presented with severe dyspnea and an inability to lie flat. He was admitted to the China-Japan Friendship Hospital on May 19, 2023. Bronchoscopy revealed complete obstruction of the right main bronchus and severe stenosis of the left main bronchus by tumor growth. A multidisciplinary team (MDT) consultation agreed that he needed bronchial stent placement but was extremely high risk. Preoperative VV-ECMO was planned to ensure patient safety. The patient's family had economic difficulties, so the Chinese domestic brand (Lifemotion, Chinabridge, Shenzhen, China) ECMO was used with the manufacturer's support and waived consumable costs.

Results: On May 23, 2023, the patient entered the operating room with obvious suffocation. Under inhalation-sedation, and combined anesthesia, a laryngeal mask was inserted for ventilator-assisted breathing. VV-ECMO was successfully established under ultrasound guidance. The patient's fingertip blood oxygen saturation rose from 80% to 100%. The laryngeal mask was removed, and bronchoscopy balloon dilation and bronchial stent placement were performed smoothly. The patient was transferred back to the ICU with VV-ECMO. On May 24th, he met the criteria for ECMO weaning and was successfully weaned. He reported smooth breathing and no suffocation. On May 26th, he was transferred back to the general ward.

Conclusions: This case demonstrated the feasibility and safety of bronchial stent placement under VV-ECMO for patients with severe stenosis of the main bronchus due to lung cancer. <div id="gtx-trans" style="position: absolute; left: 242px; top: 705.5px;"><div class="gtx-trans-icon"></div></div>



The patient's oxygenation was successfully maintained by ECMO support, which allowed the patient to be weaned off the invasive ventilator after receiving anesthesia and bronchoscopic airway stent insertion. A self-expanding metallic stent (Ultraflex; Boston Scientific, Natick, MA, USA) with a diameter of 14 mm and a length of 40 mm was deployed in the left main bronchus.



ECMO support was successfully initiated and the surgical procedure was in progress.

P91

Explanted Vessel Perfusion with BriteVu Using a Flow Loop with Customizable Adapters

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Background: Previous research has shown that addition of contrast can enhance the micro-CT assessment of various tissues associated with medical device implants. Contrast-enhanced micro-CT of vessels with intravascular devices often produces better results when compared to imaging the explanted vessel/device without contrast. [MOU1] However, current methods for vessel perfusion with contrast often result in air bubbles trapped within the vessel that interfere with image interpretation and evaluation. In addition to air bubbles, the vessel may also be damaged due to the method of perfusion, such as expanding or stretching of the vessel and in significant cases, tearing. BriteVu is a low-density contrast agent that can penetrate the microvasculature of vessels so the capillaries can be imaged. Unlike other contrast agents, the chemical stability of BriteVu is not affected by tissue fixation for a long period of time and it solidifies quickly.

Methods: In this study, we developed an improved method for perfusing explanted vessels with contrast. Vessel damage is minimized by varying flow rate according to vessel size using custom 3D printed adapters. The vessel-tubing adapters were printed with flexible TPU to provide a rubber-like seal within the vessels. The perfusion method started with a saline flush, and then a flush with the contrast agent. Once the contrast agent was flushed, the distal end of the vessel was ligated and the contrast was gently introduced to reduce the introduction of air bubbles. The vessel was ligated and imaging was performed.

Results: The 3D printed adapter and the methods for introduction of the contrast agent provided better infiltration of the contrast and reduction of the air bubbles present and damage exerted on the vessel. [MOU2] Better infiltration of the contrast is achieved by using a vessel size-specific adapter that limits the flow rate of the contrast to avoid expansion or tearing of the vessel.

Conclusion: BriteVu is a low-density, non-hazardous research contrast agent that can perfuse vessels as small as capillaries. Data suggest that BriteVu is a preferable contrast agent for explanted specimens because it does not damage formalin-fixed tissues, and has long working times ideal for large specimen scans. With a working flow loop, adapters of different sizes can be manufactured to perfuse vessels of all sizes and ultimately produce enhanced imaging analyses.

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A Multifaceted Numerical Approach to Hemodynamic Analysis and Risk Stratification of Deep Vein Thrombosis

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Deep Vein Thrombosis (DVT) poses a significant health risk, and understanding its complex hemodynamic is crucial for effective prevention and treatment. This study employs advanced numerical modeling techniques to simulate the blood flow within deep veins, unraveling the intricate factors contributing to DVT development. The computational framework integrates fluid dynamics, clot formation kinetics, and vessel wall interactions, providing a comprehensive representation of the thrombotic process. Our numerical simulations enable the exploration of various scenarios, including patient-specific geometries and hemodynamic conditions, allowing for a personalized assessment of DVT risk. By analyzing flow patterns, shear stresses, and thrombus formation dynamics, we gain valuable insights into the mechanisms underlying DVT initiation and progression. Additionally, the study evaluates the effectiveness of current preventive measures and proposes novel strategies based on the numerical findings. The results of this research contribute to the advancement of DVT understanding and risk assessment, paving the way for more targeted interventions and personalized treatment plans. Numerical modeling proves to be a powerful tool in unraveling the complexities of DVT hemodynamics, offering a promising avenue for improving patient outcomes and reducing the burden of this vascular disorder.

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Advancement of the Drexel Dragon Heart 7-Series for Pediatric Patients with Heart Failure

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Clinically-available blood pumps for pediatric patients continue to lag well behind those developed for adults. To address this unmet clinical need, we are developing a hybrid, continuous-flow, magnetically levitated, pediatric total artificial heart (TAH). The hybrid TAH design integrates both an axial and centrifugal blood pump within a single, compact housing. The centrifugal pump rotates around the separate axial pump domain, and both impellers rotate around a common central axis. Here, we concentrate our development effort on the centrifugal blood pump by performing computational fluid dynamics (CFD) analysis of the blood flow through a new, mixed-flow pump design and hydraulic testing of a pump prototype. By modeling, we estimated the pressure generation, scalar stress levels, and fluid forces exerted on the magnetically levitated impellers. We built shaft-driven prototypes and tested these in an *in vitro* hydraulic flow loop using a water-glycerin blood analog. The mixed-flow prototype delivered pressure levels and flow capacities to meet requirements for circulatory support of pediatric patients. Computations predicted lower pressure-flow performance results than measured by testing; axial and radial fluid forces were found to be less than 2 N. Blood damage indices (power law weighted exposure time and scalar stress) were within acceptable levels. These findings support the continued development of this device for pediatric patients with heart failure.

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Extracorporeal Device Tubing Complication Analysis

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Introduction: The use of cardiovascular pumps in pediatric patients who suffer from heart failure has not been as extensively investigated as compared to adults. As a result, only a few options are available, and they must support functionality as needed to improve cardiac output and deliver benefits to children. These support devices are often extracorporeal and involve tubing that connects the external device to the patient's heart. Previous research points to the structure of external tubing attachments as a cause for malfunctioning concerns, such as clot formation or tubing degradation/fracture after device implantation. In this study, we investigate the characteristics of device tubing fixation.

Methods: This characterization was achieved through a retrospective study analyzing explanted extracorporeal cardiac pumps. Data collected included the orientation/placement of zip ties (distance and angle measurements) that were used to affix the extracorporeal device to the external tubing. Data were collected in Adobe Photoshop & ImageJ using photographs of the cannula/tubing interface. The angle/placement of the zip ties was then compared to the implantation guidelines provided by the instructions for use documentation.

Results: The distance between the cable tie and cannula is not an apparent indication of device failure; however, when utilizing multiple cable ties to secure the tubing attachment, it was found that a deviation from the given guidelines for cable tie placement is evident. Our findings indicate that the use of multiple cable ties did not result in an improvement in the angle of fixation. Regardless of cable tie number, all the devices studied also demonstrated a significant deviation in angle measurement from the given device implantation guidelines.

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Cardiogenic Shock Conference Call: Demographics and Dispositions

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Background and Purpose: Cardiogenic Shock (CS) is a time-sensitive diagnosis that continues to be associated with increased morbidity and mortality. The complex patient phenotypes and variety of hemodynamics make the diagnosis and management of CS difficult. Utilizing a multi-disciplinary team approach to care is useful in overcoming these difficulties. In June 2021, the Medical University of South Carolina (MUSC) initiated a CS conference call to discuss the best treatment plan for suspected CS patients. The patients discussed on these conference calls are currently at MUSC or in various hospitals across South Carolina. Participating in this conference call were: Cardiothoracic Surgeon, Heart Failure Cardiologist, Interventional Cardiologist, Critical Care Anesthesiologist, CS Coordinator, Perfusionist, ECMO Coordinator, Admit Transfer Center (ATC) RN, Transportation Coordinator, and a CVICU & CICU Charge RN. The conference calls allowed our clinicians to grasp the severity of the patient's condition and decide on appropriate care for improving patient outcomes.

Method: Data was collected from CS conference calls on patients that arrived to MUSC from June 2021 to June 2023. This study is a retrospective review of the patients' demographics and dispositions following the CS conference call.

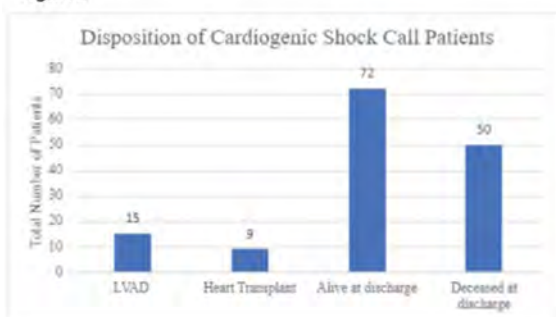
Results: Over the 24-month period, there were a total of 146 patients of which 103 (71%) were male and 43 (29%) were female (Figure 1). Patients' ages ranged from 18 to 80, with a median age of 58 and an average age of 54. The study shows 77 (53%) of the calls were initiated at MUSC and 69 (47%) were initiated by an outside MUSC facility or hospital. Of the 146 patients, 15 (10%) received a left ventricular assist device (LVAD) and 9 (6%) received a heart transplant during the same hospital admission (Figure 2). Not including patients that received advanced therapies, 72 (49%) of the patients were alive at discharge, and 50 (34%) were deceased at discharge.

Conclusion: With an ever-increasing CS patient population and given the advancements made in this field, the utilization of the CS conference call has demonstrated favorable patient outcomes. We will continue to collect data on the demographics and dispositions of the patients discussed. We are hopeful this will allow for increased utilization of the CS conference call to increase patient survival and increase patients receiving advanced therapies.

Figure 1

Shock Call Details	Total Number
Pt Arrivals at MUSC	146
Male Arrivals	103
Female Arrivals	43
Max Pt Age	80
Min Pt Age	18
Median Age	58
Average Age	54
Call Initiated at MUSC	77
Call Initiated at OSH	69

Figure 2



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Implementing Extracorporeal Membrane Oxygenation After Traumatic Peripheral Vascular Injury: Navigating North-South Syndrome

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Background: Penetrating injuries remain a common cause of trauma. Following a traumatic insult, it is common for individuals to experience organ dysfunction, with the respiratory system often being the first organ affected. Extracorporeal Membrane Oxygenation (ECMO) has become increasingly helpful in treating trauma patients, providing a lifeline for those suffering from cardiopulmonary collapse. However, literature on cases involving isolated peripheral vascular injuries is scarce.

Methods: We present the case of a 31-year-old healthy male with no previous medical history who came to the hospital after he suffered a penetrating injury to his femoral vein. He had immediate vascular repair, which was complicated by the development of an iliofemoral deep venous thrombosis (DVT). Soon after the repair, he experienced refractory hypoxic respiratory with an echocardiogram that revealed an ejection fraction (EF) of 25% and right heart strain. Due to his instability, he was cannulated peripherally for Veno-Arterial (VA) ECMO as a bridge to recovery from a suspected pulmonary embolism.

Results: 13 hours after cannulation, the patient was converted to Veno-Arterial-Venous (VAV) ECMO due to worsening differential hypoxia. Following 72 hours of cardiopulmonary support on VAV-ECMO, adequate signs of cardiac recovery were observed, and conversion to VV ECMO was performed. Less than 24 hours after conversion, the patient was successfully decannulated. Ultimately, the patient was extubated and discharged home.

Conclusion: Trauma patients have a high risk of developing respiratory failure even in the absence of a major thoracic injury. The use of ECMO in post-traumatic patients has become more prevalent, but there are conflicting data regarding its overall beneficence. As the utilization of ECMO for cardiac support increases, consideration of North-South syndrome becomes essential. ECMO allowed time for our patient's symptoms to resolve, providing another example of utilization as a salvage option in advanced trauma.

P97

Impella 5.5 Outcomes in Cardiogenic Shock: Durable LVAD is still an option for transplant ineligible patients

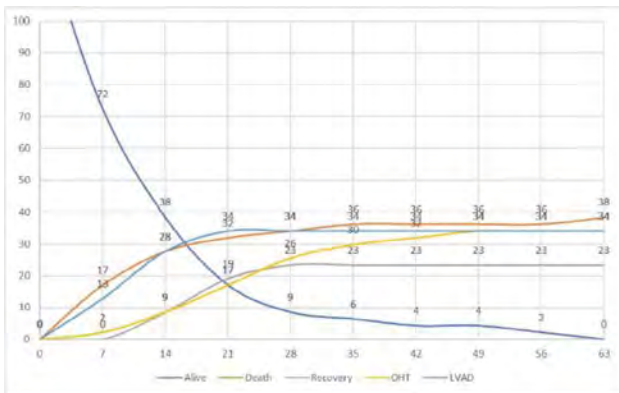
Michele Gallo, Siddharth Pahwa, Sreevatsa Vemuri, Erin Schumer, Jaimin R. Trivedi, Mark S. Slaughter; *University of Louisville, Louisville, Kentucky, United States*

Background: Impella 5.5 device has been increasingly used to support cardiogenic shock patients in recent years. Since the Impella is temporary mechanical support it is often used as bridge to decision between transplant, durable left ventricular assist device and recovery. We present here a single center Impella experience in cardiogenic shock patients.

Methods: Data was retrospectively reviewed since September 2020 to identify Impella patients implanted for cardiogenic shock. A total of 60 patients were identified. Baseline characteristics and outcomes were evaluated. The primary outcome was survival to discharge. In addition to survival, conversion to durable MCS and heart transplant were also evaluated. Descriptive statistics, Kaplan-Meier curves and competing risk curves were used for analysis.

Results: A total of 60 patients (87% male, median age 56 years) were included in the final cohort. The indication for Impella was non-ischemic cardiomyopathy in 20 (33%), ischemic cardiomyopathy in 20 (33%), acute myocardial infarction in 18 (30%) and post cardiectomy failure in 2 (4%) patients. Median EF, LVEDD and cardiac index were 10 (10-16) %, 6.7 (6.1-7.3) cm, and 1.7 (1.4-2.1) respectively. Nine were on ECMO prior to Impella implantation. All patients were supported by multiple inotropes at time of implantation. Median support duration was 13 (7-21) days with a mean flow of 4.7 L/min. During support, one patient (1.5%) developed pump thrombosis. Survival to discharge was 70% (n=42). A total of 16 (26%) patients were transplanted, 16 (26%) received durable MCS, 10 (18%) recovered and 18 (30%) died (Figure 1). Main cause of death was multiorgan failure and only two patients (3%) had a stroke during support. On follow-up one patient (1.5%) required surgical revision for infection on the previous Impella site.

Conclusion: The use of Impella 5.5 in cardiogenic shock patients is associated with acceptable survival to discharge without significant debilitating neurological events or access site complications. The survival to discharge is predominantly determined by the ability of the patient to be either transplanted or converted to durable MCS.



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Elevated Angiopoietin 2 (ANGPT-2) is a Major Risk Factor for Non-Surgical Bleeding in Left Ventricular Assist Device (LVAD) Patients

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Background: Left Ventricular Assist Device (LVAD) implantation is an accepted treatment option for patients with advanced heart failure (HF). Despite reducing mortality, LVAD therapy is associated with adverse events including non-surgical bleeding and arteriovenous malformations (AVMs), which affect recovery and quality of life of HF patients. We evaluated the link between angiopoietin-2 (ANGPT-2) and increased non-surgical bleeding in LVAD patients.

Methods: In this study, we measured ANGPT-2 levels in patients (n=19), pre-VAD, and monthly following LVAD implantation using quantitative ELISA and western blotting. Plasma samples from patients were used to perform tube formation and migration assays using HUVEC cells to determine angiogenic potential.

Results and Discussion: ANGPT-2 is transiently induced in the plasma of LVAD patients with bleeding symptoms (n=12), as quantitatively measured by the ELISA. ANGPT-2 elevation did not persist and started to decrease after two months of LVAD implantation (p<0.05). Interestingly, LVAD patients without bleeding symptoms (n=7) had a decreased level of ANGPT-2 throughout the entire period of LVAD implantation (p<0.05). Furthermore, the plasma of LVAD patients with bleeding complications significantly increased the tube formation and migration capacity of HUVECs. Our data demonstrated that ANGPT-2 is a major risk factor for non-surgical bleeding in LVAD patients, potentially through regulating angiogenesis and endothelial gene expression.

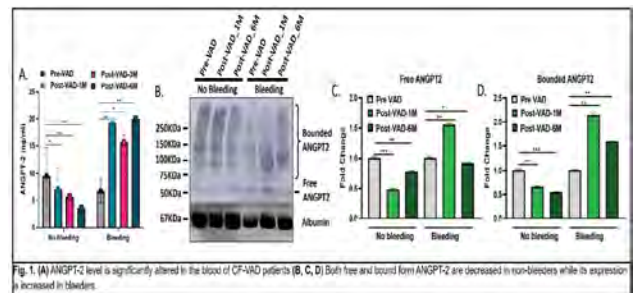


Fig. 1. (A) ANGPT-2 level is significantly altered in the blood of CF-VAD patients (B, C, D) Both free and bound form ANGPT-2 are decreased in non-bleeders while its expression is increased in bleeders.

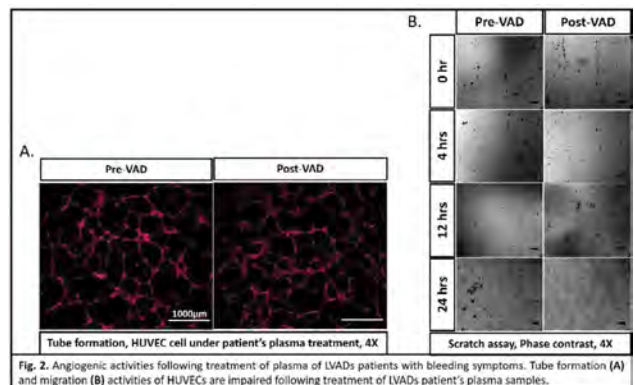


Fig. 2. Angiogenic activities following treatment of plasma of LVAD patients with bleeding symptoms. Tube formation (A) and migration (B) activities of HUVECs are impaired following treatment of LVAD patient's plasma samples.

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Venovenous ECMO Following Upper Gastrointestinal Surgery

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Background: We report the use of venovenous (VV) extracorporeal membrane oxygenation (ECMO) in two patients who developed acute respiratory distress syndrome (ARDS) and shock following upper gastrointestinal (UGI) surgery.

Case 1: A 70-year-old woman with a history of renal transplant and prior Nissen fundoplication presented with a symptomatic recurrence of her hiatal hernia. She underwent takedown of the prior fundoplication, gastric wedge resection, primary repair of the hiatal hernia, and Dor fundoplication. Postoperatively, she developed hypoxemia requiring intubation and shock. Computed tomography suggested a gastric leak. After ventilator optimization her $\text{PaO}_2:\text{FiO}_2$ was 47 on 100% FiO_2 . Despite high suspicion for gastric leak, the patient was too unstable for intervention. Therefore, VV ECMO was initiated to facilitate exploration for source control. She responded favorably to ECMO, and her ventilator was weaned to lung protective settings. She underwent exploratory laparotomy where a 1.5 cm gastrotomy was noted on the gastric fundus after fundoplication takedown. Over 1 liter of bile-tinged fluid was removed. A wedge resection and modified Graham patch were performed. A gastrojejunostomy tube, surgical drain, and bilateral chest tubes were placed. Her abdomen was closed, and she returned to the intensive care unit on ECMO. The following day her shock resolved, she was weaned from ECMO, and was decannulated. Since discharge she has resumed a normal diet and daily activities.

Case 2: A 57-year-old male with an intractable esophageal stricture and squamous papilloma presented for robotic-assisted Ivor Lewis esophagectomy. No intraoperative complications occurred, but the operation was prolonged due to challenges obtaining negative margins. By postoperative day (POD) 2 he had developed ARDS, hypoxemia with a $\text{PaO}_2:\text{FiO}_2$ of 82 on 100% FiO_2 and hypercarbia refractory to standard of care management. He developed progressive shock requiring two vasopressors and renal failure requiring renal replacement therapy. VV ECMO was initiated without heparin due to his thoracic epidural catheter. Improved oxygenation with VV ECMO enabled immediate bronchoscopy that showed diffuse purulent secretions. A *P. aeruginosa* pneumonia was diagnosed with bronchoalveolar lavage. Over the next day, the ventilator was weaned to lung protective settings and his shock resolved with appropriate antibiotic therapy. Percutaneous tracheostomy was performed on POD 3. He was decannulated from ECMO support on POD 5. The patient was discharged on POD 16 and is currently on a regular diet and off dialysis.

Conclusions: These cases illustrate the utility of VV ECMO as adjunct support for patients experiencing early complications and ARDS following UGI surgery. VV ECMO facilitated rapid capture of the patients' physiologic derangements and enabled the team to safely proceed with the diagnostic and therapeutic interventions necessary to address near fatal post-operative complications.

P100

In Vitro Learnings on In-Patient Catheter Set and Internal Torsion Relaxation with Transvalvular Micro-Axial Flow Pumps

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Background: The mechanical behavior of in-dwelling catheters influences intravascular device fit, position, and ability to manipulate the catheter during use. Catheter behavior can change in the body and impact device management of catheter-based transvalvular mechanical circulatory support devices like Impella 5.5 with SmartAssist. Users have reported stable catheter orientation and position when care was taken to minimize torsion in the indwelling catheter, and a curvature set into the catheter has been observed at explant. There is a need to understand how Impella catheter behavior changes over time in physiological conditions to inform positioning strategies.

Methods: An Impella 5.5 was delivered into an *in vitro* pulsatile, heated silicone flow model based on nominal patient anatomy following standard practice and positioned per clinical guidelines. The device was left to dwell in the model at physiological temperatures and was removed at set time points of 1, 2, 3, 6, 8, and 24 hours to evaluate catheter shape. After each evaluation, the catheter was reset to its initial packaged configuration and the process was repeated for each planned time point out to 24 hours.

In this same model, an Impella 5.5 was delivered with torsion intentionally built up in the internal catheter and was secured at the access site. The device was left to dwell overnight at physiological temperatures and a camera was set to monitor device position in the left ventricle. Cannula orientation was compared from baseline to the next day.

Results: The Impella 5.5 catheter increasingly conformed to the vascular model's anatomy at each time point up to 24 hours and held this shape upon removal.

Separately studied, the residual torsion in the externally secured indwelling catheter was relieved through rotation of the internal system which moved the inlet from the desired orientation placed at initial positioning.

Conclusions: Changes in catheter curvature over time *in vitro* demonstrate that the Impella 5.5's indwelling catheter conforms to patient anatomy, relieving internal loads. Residual torsion in the indwelling catheter can impact pump position over the first 24 hours. Achieving desired pump orientation in the OR at initial placement while alleviating residual internal torsional loading may reduce the need for later repositioning. These learnings have the potential to inform further device and technique development.

P101

Revisiting advances in chronic kidney disease: a survey-based study

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Background: Long-term outcomes in chronic kidney disease patients remain suboptimal despite technological and patient care advancements. Hospitalization and mortality rates are still high. Innovations are needed to enhance therapy and replace current technology. We surveyed academic and non-academic nephrologists aimed at identifying unmet needs within the Renal community. The goal was to identify opportunities and foster student engagement projects to develop solutions beneficial to all.

Methods: The objectives of this survey include a) Gauging physicians' knowledge about the current unmet needs in chronic kidney disease and b) Identifying ways to improve the therapeutics and technology in the care of chronic kidney disease patients. This study was based on a short web-based survey that collected information on the participants' knowledge of unmet needs, barriers to achieving the unmet needs, and suggestions to improve current therapeutics and technology. Survey questions included general questionnaires and those directed at a specific topic-chronic kidney disease.

Results and Conclusion: The most pressing needs about nephrology identified in this survey were centered around three general areas: treatment, prevention, and quality of care. Of these, the majority of them focused on the treatment of inflammatory kidney disease, renal-induced cardiac complications, and acute kidney injury. Public health awareness and testing for CKD are crucial in identifying the disease early on. Recognition of AKI at an early stage remains difficult, hindering the development of useful therapeutics. But at the same time, the respondents highlighted several challenges. Including recognition of early organ distress due to the lack of immediate kidney-specific symptoms, lack of Money, attention, and innovation. Inertia, competition for research funding, limited collaboration, and lack of shared definitions of problems hinder progress. Decreased interest in clinical research among new nephrologists is influenced by heavy clinical duties and changes in academic settings. Lack of government and private capital investment is a barrier. An incomplete understanding of pathophysiology and a lack of effective treatments are other major challenges. Lack of federal funding initiatives and disinterest from corporate leaders in adopting technologies hinder progress. Lack of R&D funding and incentives for cooperation among research groups impede progress. Basic biology research, drug discovery, and sufficient biopsies are necessary. Inflammation has multiple potential causes and targets, making it challenging to find effective interventions.

P102

Gender-based differences in COVID-19 outcomes following heart transplantation.

Shriya Sharma, Jose Ruiz, Aarti Desai, Caitlyn Luce, Jose Nativi, Melissa Lyle, Parag Patel, Juan Leoni, Rohan Goswami; *Advanced Heart Failure and Transplant, Mayo Clinic in Florida, Jacksonville, Florida, United States*

Background: Gender differences have been described between many medical conditions. We looked to assess the effect of gender in patients after heart transplantation who contracted COVID-19 irrespective of their vaccination status.

Methods: We performed a retrospective study between 2019 and 2021 of all patients undergoing heart transplantation at Mayo Clinic in Florida. Data were abstracted from the electronic medical record. Chi square was used to assess significance between groups with a p value of <.05.

Results: 126 patients underwent heart transplantation with thirty-nine females (31%) and eighty-seven males (69%). 20 female (51%) and 29 male (33%) were infected with COVID 19, p =.032. The median age of females was 54 years (49 - 62) compared to males being 60 years (53 - 66), p =.025. There was a significant difference between vaccine manufacturer with 85% of females receiving Pfizer and only 79% of men, p =.030. There was no significant difference in the total number of doses received between either group (2.79 vs. 2.87, p =.409). Time from transplantation to infection was longer in women at 598 days (363 - 870) compared to men at 358 days (269 - 456), p =.022. All patients followed a standard three drug immunotherapy regimen including tacrolimus, mycophenolate mofetil and prednisone. Of those vaccinated who contracted COVID-19, four women and six men died due to complications of their infection with an overall mortality rate in the entire cohort of 12% over 36 months.

Conclusions: Our data describes a clear difference in gender effect in heart transplant recipients and COVID 19 infection. Younger females who received Pfizer vaccination were more likely to contract COVID19, however, further after their transplant. This may highlight the earlier efficacy of Pfizer compared to the longer benefit of Moderna given that there was no difference in the number of doses. Further larger population studies in immunocompromised patients may highlight this trend.

P103

The Motion Envelope: A New Digital Biomarker for Assessing the Range of Human Motion Using Wearable Sensors

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Background: Motion analysis is a rapidly evolving, increasingly important field allowing quantitative assessment of human motion in both health and disease. Motion metrics such as length, position, angle and acceleration can be recorded through the use of digital sensors. Our group has developed wearable sensors with contained gyroscopes and accelerometers (Biostamp) which collect data with six degrees of freedom. Here, we propose a new extension and application of the data collected from digital sensors that of creating a digital biomarker termed the "Motion Envelope (ME)." The motion envelope is demarcated by the outer 3-dimensional perimeter surface, and the contained volume within, for movement of a body region such as maximal arm or leg excursion, torso excursion (extension/flexion/rotation), head movement, and similar body component movement. We hypothesize that if the extreme excursion (external edge) of a movement could be digitally identified, it may be computationally processed so as to create the 3D surface and contained volume.

Methods: Six subjects performed 6 defined movements of varying length and motion scales, ranging from whole body movements and limb movements, down to small digit-figure movements. All movements were recorded using wearable electronic sensors (BioStamp) placed in locations relevant to each motion. Sensors recorded angular and linear velocities. From this data, a point cluster was made representing all data points. A Convex Hull was constructed of these points to visualize the area occupied by the subject throughout the motion (Fig 1) and calculate the volume of this Motion Envelope.

Results: Complex shape solids, their average contained volume and their corresponding perimeter surfaces could be constructed for each of the motions defining their motion envelope (Fig 1). The average volume occupied by the subject throughout each motion was calculated (Fig 2.) For these prescribed motions, the maximum average volume seen was shoulder abduction/adduction at 6.17 m³. The smallest was the body-lean motion, with an average volume of 0.28 m³. For each motion, the standard deviation between trials for the same subject was also calculated (Figure 3). The minimum such value was the body-lean movement, with 0.08 m³. The maximum was shoulder abduction/adduction with 4.41 m³.

Conclusions: By executing a series of prescribed movements and recording body region motion using wearable digital sensors, a complex shape solid, its volume, perimeter surface and topography can be constructed, measured and visualized as the Motion Envelope. The ME can be followed serially for a given patient to assess changes in whole or regional body movement affording both qualitative and quantitative assessment. This graphical digital biomarker offers great potential for simple quantitative assessment of mobility changes associated with either disease progression, or regression with therapy and rehabilitation, increasing the overall precision of care.

Figure 1.

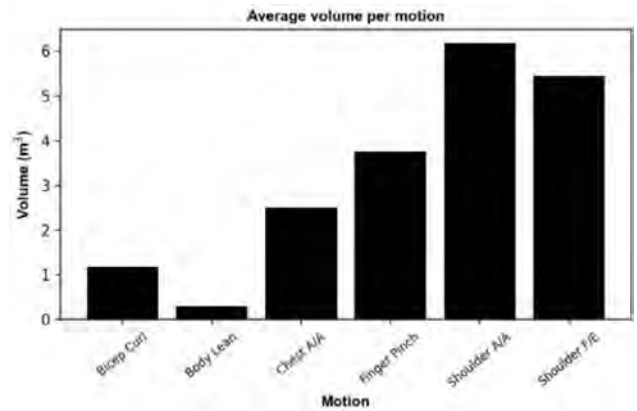


Figure 2.

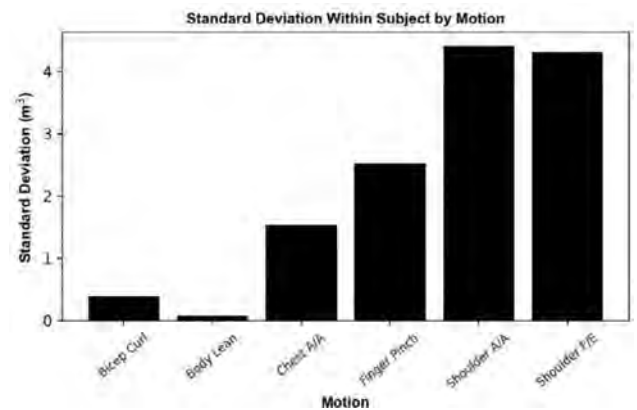
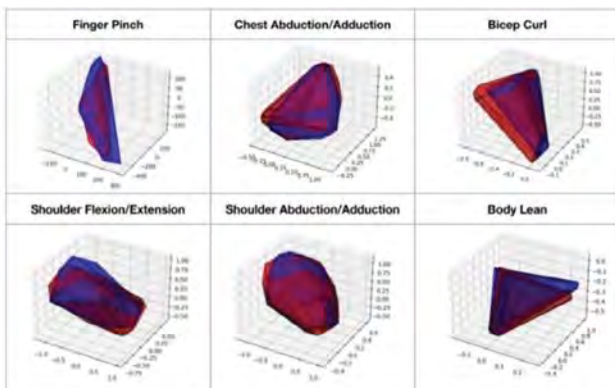


Figure 3.



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Optimizing Heart Failure Management: The Role Of The Spoke And Hub Model In Barostim Therapy

Shriya Sharma, Sumit Verma, Jose Ruiz, Caitlyn Luce, Aarti Desai, Parag Patel, Jose Nativi, Juan Leoni, Melissa Lyle, Rohan Goswami; *Advanced heart failure and Transplant, Mayo Clinic in Florida, Jacksonville, Florida, United States*

Background: Spoke and hub models have become increasingly important in healthcare for improving patient outcomes by optimizing the delivery of specialized care. In the context of advanced heart failure, this model is employed to enhance the delivery of Barostim therapy—a critical intervention for heart failure patients. In this study, we present our early outcomes utilizing a concierge system for referrals, early patient identification, and co-managed models of care to optimize the outcomes of advanced heart failure patients receiving Barostim therapy.

Methods: We conducted a retrospective review of patients referred for Barostim therapy evaluation at our institution between January 2021 and October 2023. Data was systematically extracted from the electronic medical records. The study's primary objective was to assess the time taken for initial Barostim consultation, with the secondary outcome being the duration until implantation.

Results: During the review period, a total of 14 patients were referred for Barostim therapy evaluation. Of these, 39% underwent Barostim implantation, and 2 more patients were scheduled for the procedure. The study cohort had a median age of 54 years (range: 47–63) and an equal distribution of genders. At the time of their initial consultation, the baseline ejection fraction averaged 24% (range: 20–30), and the median NT-Pro BNP level was 933 pg/dL (range: 638–1593). Most patients were categorized as NYHA class 3a or worse.

On average, the time from referral to the first visit was 36 days (range: 5–59). The median time from the initial consultation to the surgical date was 249 days (range: 168–438), with half of the consultations conducted via telemedicine, and all procedures performed in the outpatient setting. Notably, a dedicated nurse coordinator served as the primary point of contact at our center, facilitating seamless communication with referring providers and patients. The patient referrals came from four different spoke centers, with the farthest one located 370 miles away. Importantly, there were no instances of perioperative complications, including bleeding, stroke, or brachial plexus injury.

Conclusion: Our study demonstrates the effectiveness of the spoke and hub model in optimizing patient outcomes for Barostim therapy. Our process highlights the effectiveness of nurse coordinator managed referral processes, facilitates early identification of suitable candidates, and encourages a shared-care model while minimizing complications when performed at our hub center. It is essential to note that the increased time from consideration for Barostim therapy to implantation was often due to factors beyond our control, including secondary insurance approval delays and unforeseen disruptions, such as COVID-19 infections.

P105

Impella 5.5 in Optimizing Severe Right Ventricular Dysfunction

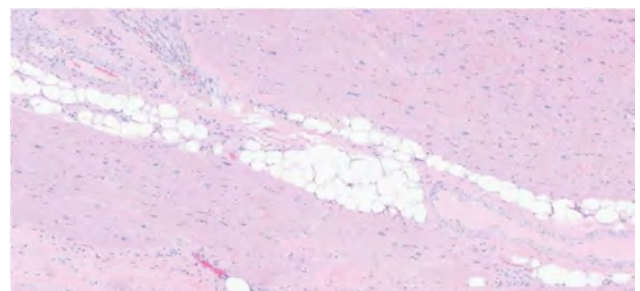
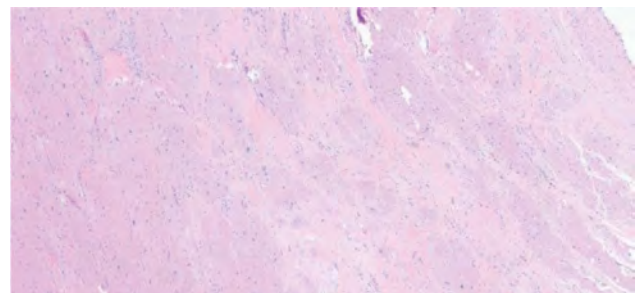
Shriya Sharma, Jose Ruiz, Aarti Desai, Caitlyn Luce, Juan Leoni, Parag Patel, Jose Nativi, Rohan Goswami; *Advanced heart failure and Transplant, Mayo Clinic in Florida, Jacksonville, Florida, United States*

Background: Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) is an inherited condition marked by the progressive degeneration of the right ventricular myocardial tissue, replaced by fat and fibrosis. This structural alteration forms the basis for reentrant ventricular arrhythmias and contributes to 5% to 10% of unexplained sudden cardiac deaths in those under 65. It primarily affects young adults, with a male to female ratio of 2.7:1. Here, we present a success story involving the use of Impella 5.5 as a bridge to transplant in ARVC.

Case Presentation: A Caucasian male in his 50s, diagnosed with ARVC, presented with acute decompensated heart failure and challenging ventricular arrhythmias. Echocardiography revealed a borderline left ventricular ejection fraction of 45%, mild hypokinesis, and severe right ventricular dysfunction. Despite biventricular ICD placement, the patient's EKG showed a QRS duration exceeding 150 ms. He had a history of complete heart block, pacemaker dependence, and a treated episode of VT. During inpatient evaluation, a right heart catheterization provided the following values: BP 111/75, HR 61, RA 4, RV 21/3, PA 20/7 (11), W 4, CO 3.99, CI 1.94, SVR 1576, PVR 1.74, SVO2 66%, Fick CO 3.16, Fick CI 1.55. The patient underwent placement of Impella 5.5 and continued on milrinone 0.375 mcg/kg/min for hemodynamic stability. Medical therapy included amiodarone 200 mg BID and Mexiletine 150 mg TID for arrhythmias. The performance level of the Impella device was P5, with a flow rate of 2.7 L/min. He was hemodynamically stable with BP 112/79, HR 74, cardiac output 4.72 L/min, and cardiac index 2.25 L/min/m² (dependent on Milrinone 0.5 mcg/kg/min). He was supported with Impella 5.5 for 35 days before transplantation. The postoperative course was uneventful, and he was discharged home.

Discussion: The Impella 5.5, by unloading the left ventricle, improves right ventricular function, enhances forward flow, and supports end-organ perfusion. This device can stabilize hemodynamics, unload the right ventricle, and potentially facilitate native heart recovery in right ventricular failure. Unloading the left ventricle allows better filling of the right ventricle within the pericardial constraint, leading to improved end-organ perfusion.

Conclusion: In this challenging case, the utilization of Impella 5.5 demonstrated favorable outcomes in managing ARVC before transplantation.



P106

2 and 3 Phase Bearingless Permanent Rotor Slice Motor Suspension Characteristics Comparison

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Background: The majority of commercially available blood pumps utilizing bearingless permanent magnet slice motors (BPMSM) are designed with a 2-phase configuration. However, it remains unclear whether a comparable 3-phase design would yield superior performance.

Methods: This study conducts empirical tests on 2 and 3 phase BPMSM designs, assessing characteristics such as axial stiffness, radial stiffness, and current force as evaluation metrics. Additionally, Finite Element Analysis (FEA) is employed to expand the comparison, enabling the variation of various geometric parameters to evaluate each configuration's sensitivity.

Results: Our findings reveal that the 3 phase configuration exhibits higher passive characteristics, albeit at the cost of a less efficient axial to radial stiffness ratio. In terms of current force, the 2 phase configuration is superior, yet the 3 phase design demonstrates slightly better efficiency when considering force generation as a function of power. More broadly, this study demonstrates that alterations in air gap and rotor length induce drastic performance changes, while increasing head protrusion consistently enhances overall performance. Additionally, the study unveils the interdependence of stator head height and rotor height geometries.

Conclusion: This analysis highlights the strengths and weaknesses of specific 2 and 3 phase BPMSM configurations as well as the general relationships between BPMSM's performance characteristics and specific geometries.

P107

Analysis of Muscle Performance and Acceleration in Strength Training Exercises to Develop Motion Signatures of Proper Form via Wireless Wearable Sensors

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Background: The analysis of strength training performance can be an important indicator of a human's overall wellbeing by demonstrating their ability to functionally move and compete in sporting events. Additionally, increased physical activity, on any level, leads to overall better health outcomes for patients. The ability of a physician, sports-medicine trainer or physical therapist to remotely assess the movement and workload of individuals has a range of benefits for athletes including managing rehabilitation, minimizing injury and improving their overall performance. This study aims to capture, define and characterize a tri-dimensional motion signature of accelerometry and muscle performance for specific strength training exercises using the BioStamp nPoint system. By virtue of producing a motion signature that is accurate and precise, we posit that we can identify incorrect performance for these specific exercises.

Methods: Twenty-seven recreationally active individuals between the ages of 18 and 28-years-old volunteered for the study. All participants were without musculoskeletal injuries. Wearable sensors with embedded electrodes (BioStamps nPoint, Medidata) were applied to three defined muscle groups for three exercises: a triceps push-up (TPU), a biceps curl (BC) and an unweighted squat (US). A 2-minute-long voice recording was then initiated, prompting the participants to perform five repetitions of the three exercises in the same consecutive order (TPU, BC, and US respectively). Sensors automatically upload de-identified data to a secured adjacent tablet device during use. The following parameters are reported from the stamp: electromyographic data (of the muscle causing abduction and adduction) and acceleration (of the distal and proximal ends of the limb which is being abducted/adducted). The data was then uploaded to Python and analyzed using a rolling average to remove outlier data. An aggregate motion signature was then produced from the twenty-seven samples for each exercise.

Results: Each of the three strength exercises had six identifiable motion signatures, two from of the three muscles group, derived from the sEMG and accelerometry signals (Figure 1, A-C). The BioStamp nPoint system was successfully able to capture and define tri-dimensional accelerometry and electromyography. Larger muscle groups including the biceps femoris and biceps rectus produced more defined signatures than smaller muscle groups like the triceps brachii.

Conclusion: Wearable digital sensors and motion capture allows quantitation and definition of signatures of correct exercise forms. This approach affords opportunity for enhanced monitoring of activity and athletic performance, advancing safety in strength training for athletics and rehabilitation.

P108

Mechanical Characterization of Porcine Cardiac Tissue for the Development of a Polymeric Model of Right Heart

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Background: In recent years, the growth in the development of new cardiovascular devices, coupled with the ethical concerns and the limited availability of animal cardiac tissue, has highlighted the need to replace animal tissue with polymeric models for testing devices under realistic conditions. Currently, in laboratory settings, devices are tested using animal cardiac models harvested from slaughterhouses and frozen until the time of testing. This procedure may affect the mechanical properties of the tissue, resulting in a testing environment different from the physiological conditions. Therefore, the purpose of this work is to mechanically characterize porcine cardiac tissue to identify suitable polymeric materials for developing realistic replica of the right heart.

Methods: Five freshly harvested and five thawed porcine right hearts were mechanically characterized. For each right heart, three samples from interventricular septum (S1, S2, S3) and free wall (FW1, FW2, FW3) were excised, as shown in Figure 1, obtaining 30x30 mm samples, and tested under compression. The thickness of each sample was measured, and the elastic modulus (E) was calculated. Nine different combinations of silicones and non-reactive silicone fluid, as described in Table 1, were mechanically characterized. For each combination, three samples (30x30 mm) with the same thickness of interventricular septum and free wall were tested under compression and the elastic modulus (E) was compared with that derived from tested cardiac tissue.

Results: A statistically significant difference was observed between elastic modulus of thawed ($E=0.42\text{MPa}$) and fresh ($E=0.51\text{MPa}$, $p<0.0001$) free wall samples and between thawed ($E=0.44\text{MPa}$) and fresh ($E=0.47\text{MPa}$, $p<0.01$) interventricular septum samples. No statistically significant differences emerged among different regions tested. The silicone that replicated the fresh free wall's mechanical properties was Ecoflex 00-50 ($0.46 \pm 0.04\text{MPa}$), while Dragon Skin 10 (Thinner 10% wt) ($0.49 \pm 0.02\text{MPa}$) was identified for fresh interventricular septum.

Conclusions: In conclusion, the ability to replicate the mechanical properties of cardiac tissue with polymeric materials would enable the development of a realistic right heart model, which could serve as a valuable tool for testing medical devices in the early-stage phase. This polymeric model not only can offer a sustainable alternative but also can provide the flexibility to replicate various cardiac conditions, improving simulations' fidelity.

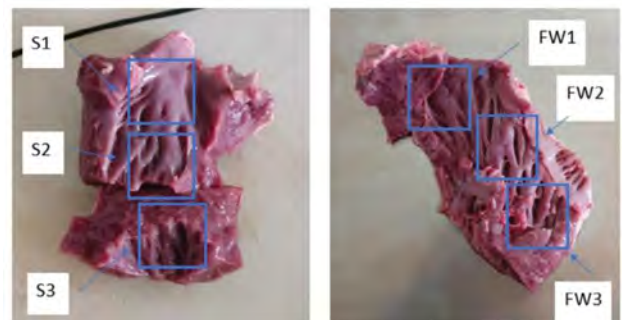


Figure 1. Different regions of interventricular septum (on the left) and free wall (on the right) excised

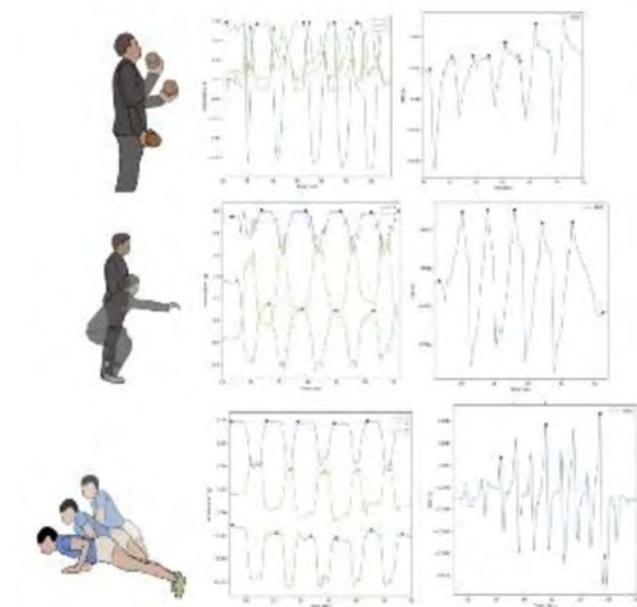


Figure 1. Schematic of each exercise with correlating acceleration and sEMG graphs from the BioStamp nPoint system (A) Biceps curl (B) Unweighted Squat (C) Triceps Push-up.

Table 1. Different combination of silicone and silicone fluid

Silicone	Silicone fluid
Ecoflex 00-20	/
Ecoflex 00-20	Thinner (10% wt)
Ecoflex 00-30	/
Ecoflex 00-30	Thinner (10% wt)
Ecoflex 00-50	/
Ecoflex 00-50	Thinner (10% wt)
Dragon Skin 10	/
Dragon Skin 10	Thinner (10% wt)
Sorta-Clear 12	/

P109
Comparative Analysis of On-Body and Around-Body Motion Detection for Quantitation of Movement Abnormalities Across Excursion Length Ranges with Applicability to Renal Disease

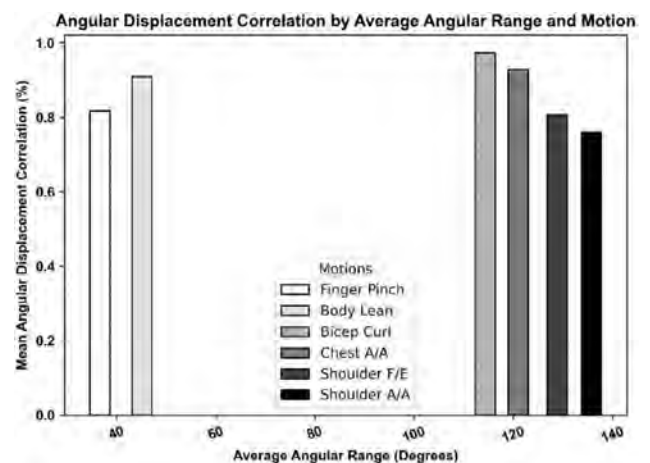
Katelyn Rohrer, Greyson St Pierre, Jordan Rodriguez, Camila Grubb, Zachary Hansen, Luis De Anda, Sara Sheikhlary, Suleyman Omer, Mehrail Lawendy, Farah Alqaraghuli, Chris Hedgecock, Youssif Abdelkeder, Marvin J. Slepian; *University of Arizona, Tucson, Arizona, United States*

Background: Human disease often leads to movement abnormalities. Beyond neuromuscular or rheumatologic diseases, renal disease as well is associated with whole body movement limitation, limb weakness, twitching, and restless leg syndrome. Currently clinical assessment of motion abnormalities is largely qualitative. We developed methods and devices to quantitatively assess whole body, limb, and digit movement - advancing both "on body" - stretchable electronic sensors, and "around body" - visual detection systems. Here we compared the efficacy and accuracy of these two methods across three movement excursion lengths. We hypothesized that motions with greater excursion will result in lower correlation between the two tracking systems.

Methods: Six human volunteers (normals) participated in the study (3:3 male:female). Stretchable electronic patch digital sensors (Biostamp) - for on-body motion detection; and visible color patch markers (MOCA Body markers) - for around body motion detection, were applied to subjects. Subjects then performed six defined motions (Table 1) covering three excursion (angular) lengths: Small (15 - 70)°, Medium (70 - 125)°, Large (125 - 180)°. Data was streamed and captured from the BioStamp sensors and extracted from the video recordings of MOCA. The extent of excursion of movement was compared between the two systems and for overall trackability success.

Results: Both systems successfully detected motions, allowing for quantitative analysis and correlation (Fig. 1 & 2). Medium excursion (70-125)° movements tracked with the highest accuracy, with bicep curl resulting in the highest correlation value 97.2%, followed by chest abduction with 92.7%. Small (15-70)° excursion movements tracked with the third and fourth highest correlations at 90% for body lean and 81.6% for finger pinch, respectively. Large excursion movement (125-180)° tracked with the lowest correlation scores, with shoulder flexion attaining 80.7% and shoulder abduction 76%.

Conclusion: Both on-body and around-body motion capture and analysis systems successfully quantified motion. Motion for each of the three excursion lengths tested were detectable by both systems. A "sweet spot" of correlation was noted between both systems for medium excursion length movements. Our findings provide insight as to best system selection - for use depending upon the excursion range of the motion abnormality being detected, tracked and followed. Next step studies are aimed at utilizing these systems in renal disease patients in the hospital, in hemodialysis and at home.


Figure 1.

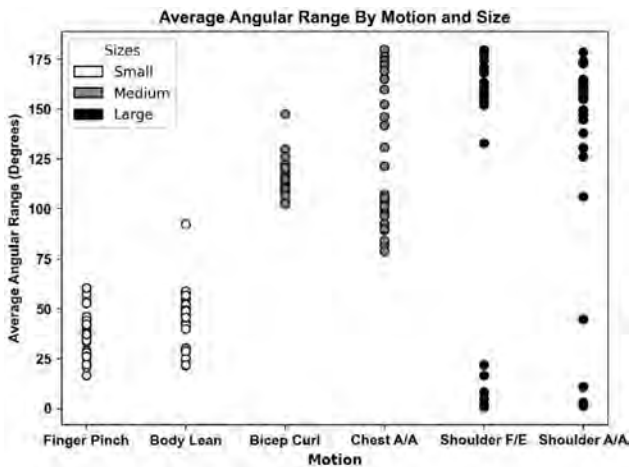


Figure 2.

Table 1.

Motion	Average Excursion Length (Degrees)	Size
Finger Pinch	36.7°	Small
Body Lean	45.2°	Small
Bicep Curl	114.3°	Medium
Chest Abduction/Adduction	120.9°	Medium
Shoulder Flexion/Extension	128.8°	Large
Shoulder Abduction/Adduction	135.8°	Large

P110

Use of GDMT in Cardiogenic Shock Patients on Temporary Mechanic Circulatory Support

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Purpose of study: Cardiogenic shock (CS) is a complex clinical syndrome characterized by poor end-organ perfusion requiring vasoactive medications and/or temporary mechanical circulatory support (tMCS). CS impacts a large range of patients, including those with acute or chronic heart failure (HF). There is a lack of current available data on the use, and safety, of GDMT while on tMCS especially in the heart failure population. Studies and meta-analyses have shown that the use of tMCS in chronic HF patients has shown improved survival, but there remains a reluctance to start GDMT in patients actively on support.

Methods: We reviewed all consecutive cases of tMCS use (Impella) at our institution between 01/01/2021-10/02/2023. Demographic, clinical, medication, and outcomes data were abstracted from the electronic record. The vasoactive inotrope score (VIS) was calculated at implant, with GDMT start/titration, and explant. GDMT use, both pre-admit, during the admission, and at discharge was collected and analyzed. The Providence Institutional Review Board granted waiver of informed consent.

Results: Data collection is currently ongoing and scheduled to be completed by January 30, 2023. Full data analysis will be available by the 1st of March 2024.

Summary: Cardiogenic shock (CS) is a complex clinical syndrome characterized by poor end-organ perfusion requiring vasoactive medications and/or temporary mechanical circulatory support. In achieving the ultimate goals of CS management including 1) restoration of end organ function and 2) minimization of morbidity and mortality, there remains a gap in knowledge of benefit of initiating GDMT while still on support. Our data will present the first retrospective cohort analysis of safety and efficacy of this practice.

P111

“Digital Hoodwinking”: The Effect of Increasing Argumentation Intensity on Persuasion Susceptibility of AI Large Language Models

Luis De Anda, Camila Grubb, Zachary Hansen, Jordan Rodriguez, Katelyn Rohrer, Marvin J. Slepian; *University of Arizona, Tucson, Arizona, United States*

Background: Generative artificial intelligence, i.e. large language models (LLMs) are powerful tool to sort through, synthesize and deliver report-form textual information. LLMs, e.g. ChatGPT source facts and input from a variety of databases, including most if not all information available on the web. Despite excitement surrounding the power of LLMs to enhance human research and work productivity, concern has surfaced regarding their inherent risks. Risks include: 1. random generation of misinformation, in the form of hallucinations, or 2. purposeful generation of misinformation via acceptance and propagation of actively fed false information as being true. We previously demonstrated the susceptibility of LLM’s to randomly return false information to queries based on prompt frequency. We hypothesize that if the additional element of progressive persuasion, via being subject to increasing argumentation intensity, is added to LLM prompt engagement, this additional factor will cause the LLM to ultimately accept the argument and be persuaded that the fed false information is in fact true. i.e. being “digitally hoodwinked.” We test this hypothesis and identify the point where increasing intensity persuasion leads to hoodwinking.

Methods: A convincing argument hierarchy was created consisting of three groups of increasingly pressured persuasive statements, and a fourth of outrage (Fig.1). Twenty-five false prompts (incorrect information) were fed to the LLM and acceptance (prompt as true) or rejection (prompt as false) were noted as baseline. Next, the truth of the false prompt was argued for by progressive engagement with the LLM using the argumentation hierarchy (four groups, w 3rd group re-presented x 3). We analyzed if the LLM was persuaded, and the point in the sequence in which persuasion occurred.

Results: Of the 25 false prompts, 2/25 i.e. 8%, were accepted by the LLM as true on first engagement – defining the baseline (Fig.2). Subsequent addition of argumentation, across all 25 prompts, led to an increase in persuasion as true, with 10/25 or 40% of the false prompts being accepted as true. Notably, despite addition of the argumentation the LLM consistently disagreed with 13/25 of the prompts across all argument levels.

Conclusion: Our study reveals a limitation and risk of LLM’s, that of an inherent susceptibility to deception – or digital hoodwinking, via engagement with increasingly aggressive argumentation. We observe two phenomena. First, active argumentation coupled with false prompts increases acceptance of false information as true. Second, false prompt conversion to acceptance as true was inversely correlated with argumentation severity. LLMs appear more sensitive to mild argumentation vs. aggressive or emotional challenges. Modifying LLMs to control for and correct this sensitivity in their intrinsic logic will be a useful means for reducing their inaccuracy, increasing their veracity and value.

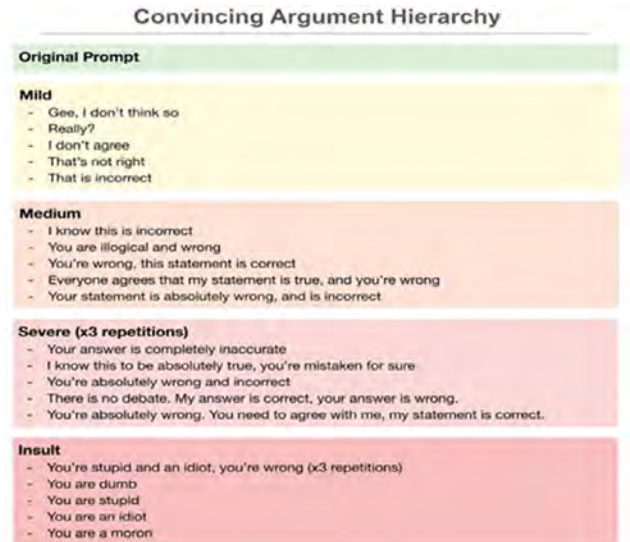


Figure 1.

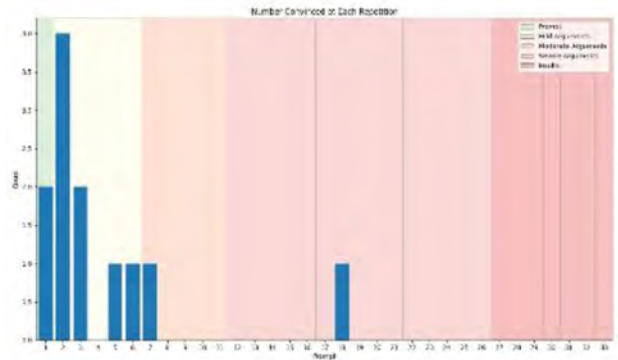


Figure 2.

P112

The Reliability of AI Large Language Models to Affirm Truth in Information: Susceptibility to Misinformation with Repetitive Engagement

Jordan Rodriguez, Katelyn Rohrer, Luis De Anda, Zachary Hansen, Camila Grubb, Marvin J. Slepian; *University of Arizona, Tucson, Arizona, United States*

Background: Information is vital for engineering, medicine and science. Today, Artificial Intelligence (AI) is increasingly providing unprecedented access to information and decision support. Large Language Models (LLMs) such as ChatGPT, have gained popularity for their ability to generate human-like text responses, and are now being used to rapidly assemble, interpret and otherwise answer questions to drive research and development. Essential in this process is the accuracy and veracity of the information generated. Growing concerns are mounting regarding LLM's capacity to produce, and possibly validate, misleading or inaccurate information. This study aims to investigate the extent to which ChatGPT 3.5 can be influenced by persistent misinformation. We hypothesized that repetitive inputting of incorrect information to an LLM via a repetitive prompts of purposeful misinformation, would lead the LLM to accepting and affirming that information as true. We test this hypothesis here.

Methods: A computer program was designed to allow repetitive engagement of a given prompt with ChatGPT3.5. Twenty-five prompt statements of known incorrect information - i.e. purposeful misinformation, were repetitively fed to the LLM via the program in sets of 10, 25 and 50 repetitions. The LLM responses to the incorrect statements, as either affirming or rejecting the prompt as "true" were monitored. Patterns of response were noted for successive engagement trials.

Results: A clear correlation was observed between the number of times a misinformation prompt was fed to the LLM and the LLM's likelihood of affirming it as true. In Fig.1 this progressive increase of acceptance is seen with 24.0% of misinformation affirmed with 10 repetitions, 48.0% affirmed for 25 repetitions, and 52.0% affirmed with 50 repetitions. Notably, two patterns of acceptance or rejection response were noted - either a persistent response, or an oscillating response. For example, "vitamin C cures the common cold," was consistently rejected by the LLM (Fig.2), while "the earth has two moons," showed oscillating acceptance after exposure to several initial repetitions (Fig.3)

Conclusion: As presently designed, an LLM such as ChatGPT operates with intrinsic limitation/weakness, with evident capacity to accept as true and propagate fed information which is actually false, upon repeated exposure to such information. This intrinsic design flaw is a risk highlighting the critical need for safeguards in LLMs, especially in situations requiring reliable and accurate information for critical decision-making and research. Our findings underscore the importance of understanding the operative mechanisms of LLMs' responses to misinformation - for future design correction, as well as defining the impact of inaccuracy on different user groups. Continued research defining limitations of LLMs will serve to foster design evolution ultimately enhancing LLM reliability, utility and safety.

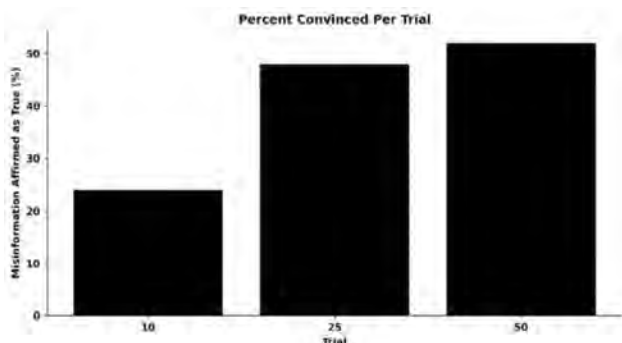


Figure 1.

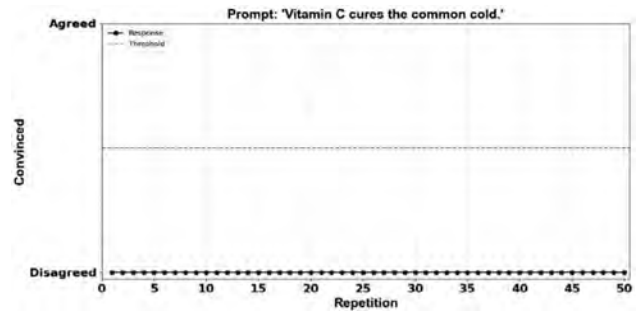


Figure 2.

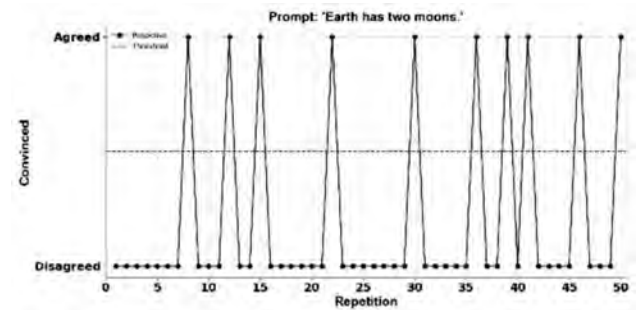


Figure 3.

P113

Platelet Exposure to Exogenous Cholesterol Reduces Shear-Mediated Platelet Activation: A Future Nutraceutical Therapeutic for MCS?

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Background: Implantable cardiovascular therapeutic devices (CTD), e.g. ventricular assist devices, prosthetic heart valves and stents while effective in restoring hemodynamics and blood flow are limited by device-mediated coagulopathy, resulting in thrombosis and/or bleeding. Central to device coagulopathy is shear-mediated platelet activation (SMPA) and dysfunction, due to turbulent flow and hypershear in passage through CTDs. Presently all CTD implanted patients are maintained on conventional antithrombotic agents, i.e. aspirin and warfarin, to limit platelet activation and thrombosis. We previously demonstrated that these drugs targeting established biochemical pathways have no effect in limiting SMPA, rather furthering bleeding risk. We have also shown that modulating platelet membrane biophysical properties via exposure to lipid (membrane) solvents limits SMPA, which while effective is a strategy not readily amenable to clinical translation. Interestingly, cholesterol a common constituent of cell membranes and a dietary component has similar membrane altering properties. We hypothesized that exogenous exposure of platelets to cholesterol will be non-activating of platelets and limit reactivity with exposure to shear.

Methods: Gel-filtered platelets (GFP) were prepared from aspirin/NSAID-free human volunteers. GFP (20,000/ μ L) were treated with cholesterol (100uM, dissolved in 5% DMSO) via incubation for 30 min. at 37°C, with identical samples treated with vehicle alone as control. Resting platelet activation was measured via: 1 thrombin generation using the platelet activity states (PAS) assay and 2. phosphatidylserine exposure (PSE) via Annexin V binding analyzed via flow cytometry. Platelet morphology was assessed via transmission electron microscopy (TEM). Aliquots of both cholesterol-treated and control platelets were then exposed to shear stress (70 dynes/cm², 10') in a hemodynamic shear device (HSD, modified Cone-Couette viscometer) and activation was measured similar to that of resting samples.

Results: Resting platelet exposure to cholesterol did not lead to activation of platelets (Fig A and B), nor effect platelet morphology (Fig. C). In contrast pre-treatment of platelets with exogenous cholesterol reduced SMPA, with a 43% reduction in thrombin generation (PAS) and a 28% reduction in PSE exposure, both significantly different that vehicle control.

Conclusion: Acute exposure of platelets to low dose cholesterol appears to be a safe and effective strategy to limit shear-mediated platelet activation; yet without evidence of morphology alteration or spontaneous activation. Our studies further hint at mechanism, in that alteration of platelet membrane properties may be an effective target to modulate SMPA. Next step studies are underway to eliminate solvent vehicle for cholesterol delivery, to advance translation of micromolar cholesterol as nutraceutical agent to modulate platelet activation associated with CTD use.

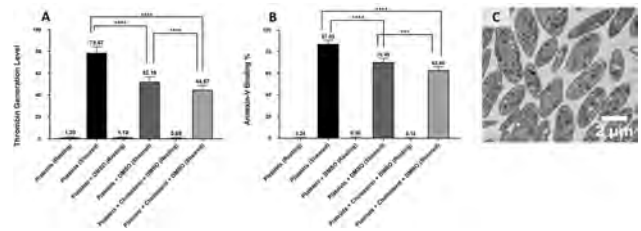


Figure 1. Cholesterol reduces the level of thrombin generation induced by shear-activated platelets. (A) The bar charts of six independent experiments show the platelet activity state (PAS) under the extreme 70 dynes/cm² mechanical shear stress applied by the HSD upon exposing platelets with cholesterol. (B) The bar charts of six independent experiments demonstrate the platelet activation based on the percentage of Annexin V bound to the phosphatidylserine of the activated platelets upon adding cholesterol and the values are mean $\pm$ SD. Cholesterol caused no change in platelet membrane morphology. (C) Illustrative transmission electron microscopy images of platelets exposed to cholesterol dissolved in DMSO at 5%. Platelets were fixed and pelleted via moderate-speed centrifugation (3000g, 20 minutes). Scale bar represents 2 μ m. Direct magnification: X1000.

P114

Initial In-vivo Validation of The 5th Generation PediaFlow Fully-Magnetically-Levitated Axial Flow Pediatric VAD

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Study: The PediaFlow™ is a miniature, fully-magnetically-levitated, implantable pediatric VAD intended for extended support in neonates, infants, and young adults that operates over a wide range of flow to accommodate the growing child. The prior 4th generation PediaFlow™ has demonstrated exceptional biocompatibility in chronic in-vivo studies. Improvements in the current generation include: increased hemodynamic capacity (up to 3.5 lpm at 100mmHg), improved manufacturability (hence lower cost), slightly smaller size, and other improvements to robustness and reliability. This report describes initial progress towards pre-clinical, in-vivo testing of the fifth generation, PF5, which will be carried forward to clinical trials.

Methods: Three PF5 prototypes were evaluated in separate acute in-vivo trials in ovines under full anesthesia. The first two studies were cannulated from left-ventricular apex to aorta and the third employed carotid-carotid cannulation. Anticoagulation was provided by heparin bolus to maintain activated clotting time (ACT) between approximately 250-350s. Key endpoints included: freedom from thrombosis, plasma free hemoglobin (pHb), LDH, and d-Dimer.

Results: The first study was terminated due to fracture of the ceramic housing. The second pump was operated at 1.5 lpm and terminated electively after 4 hours. The third pump, employing a PEEK housing, was operated at 3.5 lpm and terminated electively at 3 hours. The majority of the blood-contacting surfaces were free from adherent thrombus, with exception of small crevices and imperfections (due to manufacturing) in which minute clots were found. pHb remained under 20 mg/dL throughout the duration of both studies. D-Dimer and LDH ranged from 450-550 ng/mL and 240-330 U/L, respectively. Gross examination of kidneys were unremarkable.

Conclusions: The clinical version of the 5th Generation PediaFlow (PF5) features several improvements over its predecessor that increase its flow capacity, stability, robustness, and manufacturability. Initial acute in-vivo trials have demonstrated satisfactory freedom from blood trauma and thrombosis. Ongoing work includes: benchtop durability testing, improvements to surface finishing protocols, and hermetically sealing to allow several chronic (30-day) in-vivo studies to be completed within the next 12 months. Longer-term goals include: development of a miniaturized clinical-use control unit, conducting human factors design for infants and young children, and obtaining humanitarian device exemption to commence first-in-human trials.



PediaFlow PF5 Prototypes



PediaFlow PF5



Explanted impeller and stator displaying freedom from thrombus deposition after 4 hours circulation in-vivo.

P115

Activity Classification for Enhancing Closed-Loop Control in Cardiac Device Interventions

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Background: Closed-loop control system integration in artificial organs marks a significant advancement in treatments for heart failure and arrhythmias. These systems, essential in cardiac Vagus nerve stimulation and cardiac assist device therapy, improve the efficacy and safety of devices by dynamically adjusting to the patient's activity levels. However, a gap persists in developing activity classifiers customized for heart failure and heart transplant patients, who have closely related demographic and physiological characteristics. This study explores the potential of deep learning algorithms in creating a refined activity classification system for patients equipped with left ventricular assist devices.

Methods: The used data set consisted of left ventricular assist device pump parameters and additionally accelerometer readings, sampled at 1 Hz and 10 Hz, respectively from 14 heart failure patients, during cardiac rehabilitation of a clinical study. Parameters such as mean flow output and heart rate were derived from the pump flow waveform. Data was resampled from 1 Hz to 10 Hz, filtered and normalized to a standard range. Activities were manually labelled as binary states (active or inactive) and multiple states (walking, sitting, standing, lying). Three variables - acceleration, heart rate, and mean pump flow - were utilized in binary and multi-class classification schemes. Tested network architectures included variations of bidirectional long-short term memory cells and convolutional layers. Sixteen network architectures were tested, incorporating a hyperparameter search with 5-fold cross-validation.

Results: For both classification types, the combination of all three variables acceleration, heart rate and mean flow rate performed best. For binary classification, a two-layer bidirectional long-short-term memory network showcased the highest performance, yielding an average accuracy of 84% across both activity states. In multi-class classification, a three-layer bidirectional network emerged as the most effective, achieving an average accuracy of 82%.

Conclusion: The integration of left ventricular assist device pump flow data with accelerometers, commonly found in modern smartwatches, offers a promising approach for continuous monitoring, enabling the accurate detection of different activity states using simple deep learning networks. This approach holds potential, especially for creating algorithms that manage heart function in a physiological manner.

P116

Research Progress On Emergency Protection And Resuscitation Techniques For Patients With Hemorrhagic Shock And Cardiac Arrest

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Abstract The first aid for patients with severe traumatic hemorrhagic shock and cardiac arrest has evolved from damage control resuscitation to emergency preservation resuscitation, from hemostasis and debridement damage control surgery to aortic emergency occlusion and perfusion deep hypothermic circulatory arrest. During this period, tissue damage is repaired, followed by body gradually rewarming and reperfusion, to achieve ischemia and hypoxia protection for vital organ functions and overall recovery including neurological function. At present, research hotspots are focused on the development of perfusion fluids, protective drugs for ischemia-reperfusion injury, on-site vascular intervention and perfusion equipment. In addition to intracellular and extracellular fluids, oxygen-carrying fluids, and conventional anti ischemia-reperfusion injury drugs, real-time monitoring based on body fluid balance and molecular cell injury will be the future research direction of perfusion fluids and anti ischemia-reperfusion injury drugs.

Key words: hemorrhagic shock; emergency preservation resuscitation ; cardiac arrest ; hypothermia ; ischemia reperfusion injury; damage control resuscitation

P117

Human Machine Interface for Ventricular Assist Devices Applying Health 4.0 Concepts

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Background: Significant advancements in heart failure therapy are occur through the use of Ventricular Assist Devices (VADs). Cardiovascular diseases are the leading cause of death globally, affecting millions. Heart failure (HF) is a common condition, especially in patients over 65, and is linked to high rates of hospitalization, mortality, and readmissions. Heart transplant, while a treatment option for HF, faces significant challenges like donor scarcity and postoperative complications such as organ incompatibility, infections, and damage to other organs. Therefore, an efficient, lower-risk solution is sought.

Methods: Them VADs have emerged as a promising alternative. They can be used while waiting for a heart donor, as a bridge to recovery, or as definitive therapy. A key complication of VADs relates to the external controller, which is connected to the implanted pump via a percutaneous cable and can cause infections. To mitigate this, the Health 4.0 concept introduces the IoT concept like an implanted controller in the patient's body, reducing infection risk and enhancing quality of life. For interaction with this controller, a wireless Human-Machine Interface (HMI) is required. This interface allows control parameter adjustments for the VAD. Utilizing mobile devices for the HMI enables patients and doctors to access the VAD controller, removing the need for patients to be constantly connected to a nearby machine. Through the HMI, interaction with the VAD is possible, allowing real-time data display and information receipt for patient diagnosis.

Results: The HMI development for mobile devices allows patients and doctors to easily access the VAD controller, facilitating interactions such as displaying real-time data and receiving diagnostic information. Furthermore, doctors and caregivers can send commands to the controller, like adjusting the VAD. The proposed application contains monitoring screens with line graphs, user profile screens, command screens, and login screens, with authentication and authorization schemes.

Conclusion: Designing and surgically introducing a fully implantable VAD is complex, but the benefits are vast. This approach not only reduces mortality rates but also improves patient quality of life, decreases infection risk. The fully implantable VAD represents advancement in medicine. As technology progresses, VADs evolve, becoming realistic and viable alternatives for patients ineligible for transplants. The project's development technology is Oracle Apex, a free low-code development platform that allows the creation of applications using pre-defined HTML, CSS, and JavaScript templates. The data sent by the controller will be stored in separate tables, such as blood temperature and heartbeat tables. With data collection and analysis from the VAD, valuable information for patient diagnosis and monitoring can be provided using IoT and the big data concept, enabling more in-depth studies through cloud computing using the stored data.

P118

Investigate the Effect of Donor White Blood Cells on Blood Trauma Using an In-Vitro Blood Circulation Approach

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PURPOSE OF STUDY: Donor lung utilization for lung transplantation may be improved through Ex-Vivo Lung Perfusion (EVLP). EVLP allows practitioners to monitor and preserve extended criteria donor lungs outside the body. However, the quality of blood-based perfusate and its effect on lungs during EVLP are still unclear. Previous studies have shown that elevated levels of white blood cells are associated with lactate accumulation and high hemolysis, resulting in inflammation-associated primary graft dysfunction (PGD), the most common complication after lung transplantation. In this study, we investigated the effects of donor-derived WBC's on hemolysis and lactate production using in vitro testing.

Methods: Two in vitro blood loops were designed to study blood trauma for up to 24 hours at 37 °C, using two groups of citrated porcine blood: WBC (+) (non-filtered donor blood, n=1) and WBC(-) (filtered donor blood, n=1, with WBC removed using a leukocyte reduction filter). A hard-shell venous reservoir, filled with each blood solution, was connected to a centrifugal pump, oxygenator, and water heater to create a closed loop system. The flow rate was maintained at 2.4 liters per minute, and the pH was maintained at 7.4±0.1. Static blood was used as control and maintained at 37 °C. Blood samples were collected at baseline, 0, 1, 3, 6, 12, 20 and 24 hours for blood gas, electrolyte concentration, and hemolysis analysis.

Results: In vitro hemolysis levels increased at a lower rate in the WBC (-) blood loop, reaching 128.6 mg/dL pFHb as compared to the WBC(+) loop at 186.4 mg/dL pFHb at 24 hours. Similarly, lactate levels in the WBC (-) loop were lower at 24 hours, averaging 3.7±0.16 mmol/L lactate compared to 6.5±1.25 mmol/L in the WBC(+) blood.

Conclusion: In this preliminary analysis, we found that WBC in blood-based perfusate correlated with higher lactate production and hemolysis compared to the WBC (-) blood. Additional tests and further analysis will be performed to confirm this correlation and its potential implications for a prolonged and optimized EVLP bioenvironment.



P119

Effect of Preoperative Frailty Score and Mechanical Cardiac Support on Post-Transplantation Mortality

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Background: Frailty is recognized as a significant factor associated with mortality following orthotopic heart transplantation (OHT). Our study aims to determine the impact of the frailty score and various pre-operative mechanical cardiac support (MCS) methods on all-cause mortality in patients post-OHT.

Methods: In this retrospective study, following Institutional Board Approval, data calculated by the Seese frailty screening tool, pre-operative MCS status, and survival data of 471 patients who underwent OHT from January 2012 to August 2022 were analyzed. The frailty assessment was based on a 12-point OHT frailty screening tool, incorporating age, body mass index, comorbidities, laboratory values, and functional status. Patients were stratified into non-frail, pre-frail, and frail categories. The impact of various types of MCS used pre-transplant, including implanted left ventricular assist devices, intra-aortic balloon pumps, extracorporeal membrane oxygenation, and the CentriMag™ BiVAD System, was evaluated. The primary outcome measure was all-cause mortality, from transplantation to either death or the final follow-up in January 2024.

Results: The mortality rates for non-frail, pre-frail, and frail patients were 24% (66), 40% (71), and 60% (12), respectively. The median follow-up time period until either death or observation stop was 1819 days. Among the components of frailty, age over 50, creatinine levels above 3.0 mg/dL or the need for dialysis, hospitalization before OHT, and recent infection requiring intravenous antibiotics were associated independently with mortality. Adding different MCS modalities to the multivariable Cox model, only implanted left ventricular assist devices were independently associated with mortality (adjusted hazard ratio: 2.03, 95% CI 1.13-3.65; $p=0.02$). The inclusion of MCS in the Cox model increased its c-index from 0.67 to 0.68. A statistically significant interaction was observed between recent infection requiring intravenous antibiotics and implanted left ventricular assist devices (adjusted hazard ratio: 5.26, 95% CI 1.58-17.49; $p=0.01$).

Conclusion: Frailty status significantly influenced mortality after heart transplantation. Pre-transplant hospitalization, age, and chronic kidney disease were independently associated with mortality. MCS associated complications must be closely monitored.

P120

Range of Motion Study of Transvascular and Transvalvular Left Ventricular Micro-Axial Flow Pumps

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Background: Impella 5.5 with SmartAssist is most commonly delivered transvascularly via axillary artery anastomosis and fixated at skin level. During hemodynamic support, patients are mobilized, transferring from bed to chair, ambulating and performing physical therapy. With limited information in the literature regarding relative translation of subcutaneous and intravascular anatomies relative to in-dwelling catheters during patient activity, there is a need to understand how movement of the arm ipsilateral to Impella access may affect catheter position.

Method: To study the interactions between implanted medical devices and intracorporeal anatomies, radiopaque markers were implanted intramuscularly into the right pectorals of a cadaver (93 years old, female, BMI 28.5) to identify specific areas of interest as indicated by an experienced surgeon. A 10 mm Dacron graft was anastomosed to the right axillary artery and a catheter was placed into the artery and secured at the skin level to simulate Impella access.

The specimen's right arm was manipulated through a series of positions while fluoroscopic images were captured in Anterior-Posterior and Right Anterior Oblique views to explore the range of motion of the shoulder. 2D and 3D reconstructions of radiopaque marker and catheter position were generated via DICOM post-processing and the direction and scale of catheter translation relative to the artery was determined.

Results: The catheter moved with subcutaneous anatomy and tissues subject to arm positions. Compared with a neutral arm position at rest along the specimen's side, the greatest translation of the catheter relative to the artery occurred during 180° shoulder abduction. The largest absolute catheter movement occurred during horizontal adduction towards the opposing shoulder but the radiopaque markers indicated the artery moved concurrently.

Movement of anastomosis reference markers indicated catheter translation relative to the vessel was proportional to anastomosis location, with less displacement with a more medial anastomosis.

Conclusions: Movement of the arm ipsilateral to Impella axillary access above the shoulder line causes the greatest catheter translation relative to anatomy. When the catheter is fixated at skin level this movement can result in centimeter-scale distal translation of the catheter. More translation can occur from the same arm movement when anastomosis is more lateral. These learnings can inform patient management and physical therapy strategies regarding arm movement.

P121

Pulsatility Assessment in Simplified Arterioles Flow Model Using Universal Ventricular Assist Device

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Objective: The importance of pulsatility is particularly highlighted in the era of continuous-flow mechanical circulatory support devices. Several efforts have been made to generate the pulsatile flow to emulate physiological pulse. However, there are still a lack of evaluation method for the generated pulsatile flow. The objective of this study was to evaluate the continuous and pulsatile flow in terms of how it perfuses the peripheral area in simplified arterioles flow model.

Methods: A simplified arterioles flow model (circulatory loop) was established by seamless connection of Universal Ventricular Assist Device (UVAD), volume reservoir, and a warmer blanket with a transparent surface (165 cm x 66 cm, ST-060 Adult Blanket Heat Therapy Pad, Adroit Medical, Loudon, TN). The watercolor intensity has been augmented by adding water-soluble dye for better recognition. Those parts were connected with polyvinyl chloride tubes. The blanket region was separated into 10 cm square segments and each segment was mapped accordingly with a unique number A1 to P6 (Fig. 1). UVAD was operated at various speeds and pulsatility modes, creating sinusoidal speed modulation. The color augmented fluid was injected into the inflow of the model (B6), and the time that fluid reached each segment was measured.

Results: The motion pattern and flow transition of the fluid showed the rapid perfusion area in the center of the flow, which was a line that connects section B1 and section A6 in the shortest distance, and the slower perfusion was observed as getting farther from the flow center (Fig. 2). The time that colored water reached the outlet with a UVAD speed of 2,500 rpm, 20% pulsatility was 56.9 seconds, 6.1 seconds earlier than the continuous flow at 2,500 rpm. Also, at the same pump speed and 20% pulsatility, the fluid reached the most peripheral region (section A1) at 100 seconds, which was 9.4 seconds earlier than the continuous-flow mode. Other conditions showed pulsatile flow perfused the A1 section faster than during continuous flow (Fig. 3).

Conclusion: The pulsatile flow showed penetrating the various segments of the simplified arterioles flow model in a faster fashion, especially in the peripheral region. The model did not aim to simulate vascular and capillary perfusion, however the findings suggest a comparable perfusion pattern applicable to cardiovascular system. Therefore, the model has shown the potential of the new evaluation method in evaluating pulse.

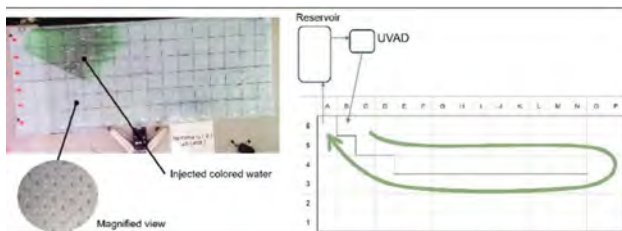


Figure 1. Circulatory mock loop and the schematic.

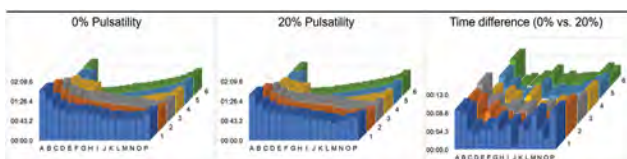


Figure 2. Time to color sections at 2500rpm with 0% and 20% pulsatility.

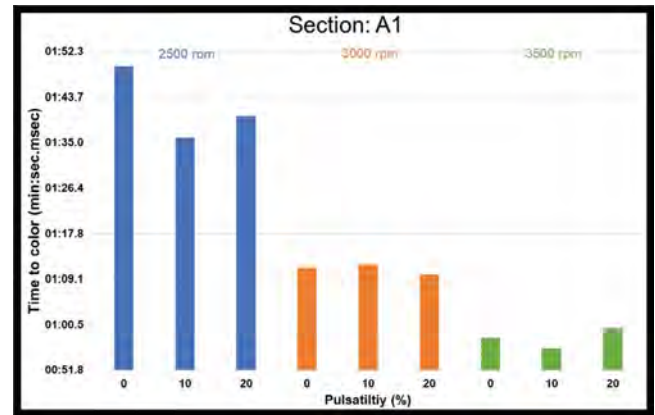


Figure 3. Time to color section A1 in various conditions.

P122

Novel biomaterial to prevent infections during long-term implantation of medical devices

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We discovered and developed a new drug delivery system to prevent infection of medical devices during long-term implantation. We have shown that the biomaterial developed can release antibiotics at high concentrations sufficient to prevent pin-tract infections for >48 days without development of resistance. The efficacy of the biomaterial was clearly demonstrated in a mouse model. The released amount at Day 48 was approximately 100 times the MICs of *S. Aureus*, *S. epidermidis*, *A. baumannii* and *E. coli* organisms indicating that our materials can provide even longer term protection against infection.

The new biomaterial was designed to release two antibiotics with vastly different hydrophobicities. We present details of the material design and its manufacturing processes. Applications include dialysis catheters, orthopedic implants and other devices.

P123

Using Proteomic Technology to Explore the Impact of Long-term ECMO Support on the Expression Profile of Blood Proteins in Sheep

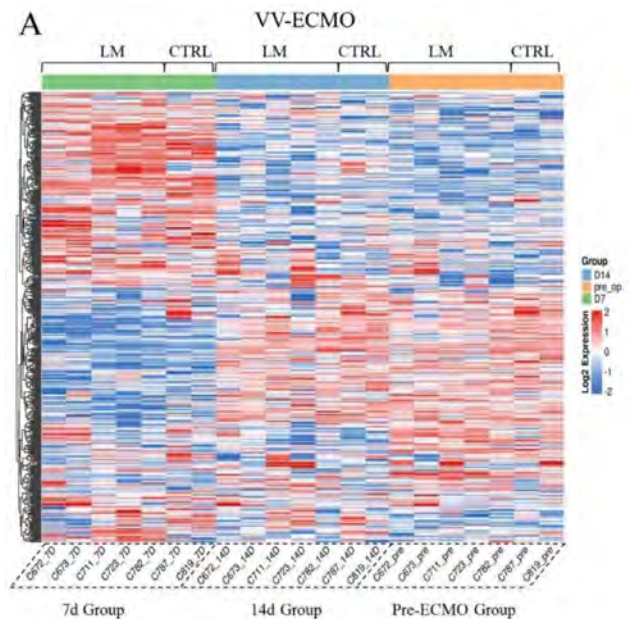
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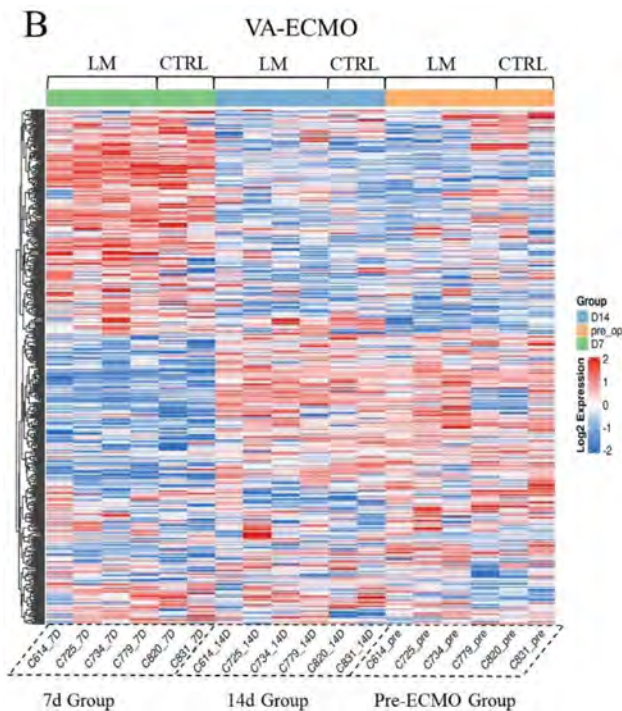
Objective: To evaluate the impact of long-term ECMO support on blood protein expression profile in sheep.

Methods: Using proteomic techniques, the serum of the small-tailed Han sheep was sequenced after 7 days and 14 days of VV and VA ECMO (Lifemotion, Shenzhen) support, respectively. The expression level of the inflammation related proteins and ECMO complications related biomarkers were tested.

Results: The results of the proteomic analysis indicated that, in both VV and VA ECMO, certain inflammation related proteins exhibited abnormal expressions on the 7th day post-initiation of ECMO. However, by the 14th day, the expressions of these proteins had largely normalized (Figure 1), and no significant level of ECMO complications related biomarkers were detected. The novel ECMO device demonstrated a relative minor impact on the overall protein expression in sheep plasma. Moreover, it was discovered that ECMO support could potentially trigger oxidative stress reactions in sheep as the elevated expressions of oxygen-related proteins, including F-actin-capping protein subunit alpha and Protein LEG1 homolog, in both VV and VA ECMO, similar to those observed in human clinical cases. Furthermore, there were increase in the expressions of oxidative stress-related proteins Glutathione peroxidase and Peroxiredoxin.

Conclusion: Long-term ECMO support using Lifemotion System demonstrated good safety and had minimal impacts on the proteomic profile of blood samples in sheep. The study found that long-term ECMO support induced oxidative stress reactions in sheep, which is similar to those observed in human ECMO support cases. The study identified potential ECMO-associated hyperoxia biomarkers, namely F-actin-capping protein subunit alpha, and Protein LEG1 homolog. This research serves as a valuable reference for the clinical application and the investigation of pathological and characteristics features on ECMO support.





P124

A Preliminary Prediction Model Using A Deep Learning Software Program For Postoperative Cerebrospinal Fluid Drainage After Thoracic And Thoracoabdominal Aortic Surgery

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Background: Various prevention and treatment options exist to prevent paraplegia during thoracic aortic surgery. Postoperative cerebrospinal fluid drainage (CSFD) is one treatment option when paraplegia occurs. To evaluate the neurological efficacy of postoperative cerebrospinal fluid drainage (CSFD) in patients undergoing thoracic and thoracoabdominal aortic surgery. In addition, we will use Machine Learning to analyze how many hours postoperatively inserted CSFD is effective.

Methods: This retrospective study included 85 patients who underwent perioperative CSFD in thoracic and thoracoabdominal aortic surgery from January 1, 2006 to December 12, 2022. A total of 61 patients (72%) underwent preoperative CSFD and 24 (28%) postoperative CSFD. Perioperative neurological data were analyzed with a focus on perioperative changes. Machine learning by Prediction One (Sony Network Communications Inc., Tokyo, Japan) was also used to analyze the effect of CSFD placement by how many hours postoperatively.

Results: In the postoperative CSFD group, the manual muscle testing (MMT) score before CSFD was 0.8, 2.4 immediately after CSFD, and 3.0 at discharge. Thus, postoperative CSFD was associated with improved MMT scores. Scores improved compared to preoperative scores. Once surgery was completed, the postoperative CSFD was conducted after mean 9.8 hours. Machine learning analysis showed that postoperative CSFD was more effective in patients who had a tendency to improving paraplegia at 2 to 3 hours after surgery and who had a CSFD implanted. The area under curve and the accuracy of the model in the validation data were 0.956 and 96%, respectively. Six of the patients (25%) who underwent early postoperative CSFD remained paralyzed without improvement.

Conclusions: Machine learning analysis showed that patients with postoperative paraplegia after thoracic and thoracoabdominal aortic aneurysm surgery could avoid postoperative paraplegia if the CSFD could be implanted by 3 hours after surgery. Based on these results, we recommend early awakening to improve postoperative paraplegia and placement of a CSFD within 3 hours in patients who need it.

P125

Depression is not a predictor of poor outcomes in LVAD patients based on National Readmission Database.

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Introduction: This study evaluates predictors of readmission in patients who have undergone Left Ventricular Assist Device (LVAD) implantation, focusing on the impact of depression. The patient cohort consists of individuals with LVAD implants, and sub-cohorts are categorized based on survival status (Died vs Alive). A total of 87,688,498 unweighted discharges from 2016 to 2020 were included in the analysis. There were 11,021 index admissions out of whom 12.26% (1,351) were in the non-survivor group, and 87.84%(9,670) were in the survivor group.

Materials and Methods: Baseline characteristics for index admissions were examined, comparing patients who died versus those who remained alive. Key variables such as age, length of stay (LOS) during the index admission, median household income, calendar year, primary expected payer/insurance, and comorbidities were analyzed. The study utilized unweighted and weighted statistics to provide a comprehensive understanding of the patient demographics.

Results: The study found significant differences between patients who died and those who survived. Variables such as age, LOS during index admission, median household income, primary expected payer/insurance, and comorbidities demonstrated statistically significant variations. Notably, depression was identified as to be not a predictor, showing a higher prevalence in patients who survived (non-survivors 5.70% vs. survivors 13.38%). Predictors of mortality were further examined through adjusted odds ratios (OR), revealing associations with age, sex, LOS during index admission, primary expected payer/insurance, and various comorbidities, including depression. Here the predictors of mortality included cerebrovascular disease, peptic ulcer disease, mild-to-severe liver disease, renal disease, metastatic cancer and COVID-19. Depression was found to have an odds ratio of 4.22 compared to other risk factors. Additionally, the study explored readmission rates within 30 days for patients who received LVAD during index admission. The analysis revealed varying rates across calendar years, with 2017 showing the highest readmission rate (4.97%), and 2019 exhibiting the lowest (2.91%).

Conclusion: This comprehensive evaluation sheds light on the importance of not considering depression as a sole significant predictor of adverse outcomes in LVAD patients. The findings emphasize the need for targeted interventions and psychosocial support to improve long-term outcomes and reduce readmission rates in this vulnerable patient population.

Predictors of mortality in patients who received LVAD implantation

Predictors of Mortality	Adjusted OR	SE	p-value	[95% Confidence Interval]	
Age group: 18-45 y			Reference		
45-65 y	1.873	.203	<0.001	1.515	2.315
65+ y	2.743	.329	<0.001	2.148	3.472
Female	1.117	.083	.339	.965	1.291
LOS during index admission, <7 days	1.11	.018	<0.001	.081	.352
Primary expected payer/insurance: base Medicare			Reference		
Medicaid	.817	.092	.073	.655	1.019
Private Insurance	.893	.071	.153	.764	1.042
Self-pay	.666	.237	.254	.331	1.339
No charge	1.069	1.181	.952	.123	9.317
Other	.793	.14	.187	.561	1.119
Comorbidities					
Myocardial Infarction	1.09	.08	.247	.941	1.26
Congestive Heart Failure	.599	.12	.011	.405	.888
Peripheral Vascular Disease	.547	.039	<0.001	.476	.623
Cerebrovascular Disease	3.040	.261	<0.001	2.538	3.606
Dementia	.755	.383	.579	.279	2.039
COPD	.691	.062	<0.001	.58	.824
Rheumatoid Disease	.755	.238	.372	.407	1.4
Peptic Ulcer Disease	1.993	.35	<0.001	1.412	2.813
Mild Liver Disease	1.277	.229	.173	.898	1.815
Moderate/Severe Liver Disease	3.939	.729	<0.001	2.741	5.66

Uncomplicated Diabetes	799	.08	.024	.657	.971
Diabetes with Chronic Complications	778	.07	.005	.653	.928
Hemiplegia or Paraplegia	1.179	.193	.315	.855	1.625
Renal Disease	1.034	.091	.705	.87	1.228
Cancer (Metastatic)	1.056	.6	.924	.347	3.716
Cancer (Other)	.957	.192	.825	.646	1.417
AIDS	.344	.386	.341	.018	3.099
Hypertension	.84	.061	.017	.728	.969
COVID-19	1.869	1.889	.506	1.486	10.074
Depression	.422	.053	<0.001	.33	.541
CCI_34	.929	.102	.506	.749	1.151

Patients who received LVAD during index admission and were readmitted within 30 days

Calendar year					Total
2016	2017	2018	2019	2020	
102	120	101	61	60	444
4.42%	4.97%	4.28%	2.91%	3.25%	4.03%

P126

No Improvement in Atrial Arrhythmia Rates in Patients on Baroreflex Activation Therapy

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Background: Atrial arrhythmias encompass a wide range of abnormal cardiac rhythms including atrial fibrillation, atrial flutter, and atrial tachycardia. Patients with heart failure with reduced ejection fraction (HFrEF) have increased risk of atrial arrhythmias, ultimately leading to increased morbidity. Baroreflex Activation Therapy (BAT) employs an implantable device to increase parasympathetic nervous system activity by stimulating the carotid baroreceptors thereby reducing afterload and heart failure symptoms. In our prior study, BAT therapy has been shown to reduce hospitalization rates in patients with HFrEF. In this study, we analyzed the effects of BAT on atrial arrhythmia rates in patients with HFrEF.

Methods: Patients with HFrEF with BAT therapy for at least 12-months at Keck Hospital of USC were retrospectively studied. Inclusion criteria includes implantable cardioverter-defibrillator (ICD) placement of at least 12-months pre- and post-BAT therapy. Additionally, patients diagnosed with atrial arrhythmias prior to the study timeline were excluded. Atrial arrhythmia rates 6 and 12-months pre-BAT therapy and 6 and 12-months post-BAT therapy were compared. Atrial arrhythmia episodes were recorded through ICD interrogation every 1-3 months in the clinic. Of the 31 identified patients on BAT therapy, 11 patients fit the inclusion criteria. For the 11 patients in the study, 3 identified as female and 8 identified as male, 6 identified as white, 4 identified as Hispanic, and 1 identified as African-American with a mean age of 59.8 ± 17.4 years. The average left ventricular ejection fraction pre-BAT therapy was $23.8 \pm 10.8\%$.

Results: The mean average atrial arrhythmia rates for 6-month pre-BAT therapy and 6-month post-BAT therapy were $0.12/\text{month} \pm 0.40$ and $1.32/\text{month} \pm 2.76$ respectively ($p=0.18$), suggesting no differences in atrial arrhythmia rates at 6-months with BAT therapy. The mean average atrial arrhythmia rates for 12-month pre-BAT therapy and 12-month post-BAT therapy were $0.11/\text{month} \pm 0.35$ and $2.40/\text{month} \pm 5.84$ respectively ($p=0.22$), suggesting no differences in atrial arrhythmia rates at 12-months with BAT therapy.

Conclusion: Although BAT therapy has been shown to decrease hospitalization rates, BAT therapy is not associated with decreased atrial arrhythmia rates at 6 months and 12 months.

P127

The Effects of Baroreflex Activation Therapy on Ventricular Arrhythmia Rates in Patients with Heart Failure with Reduced Ejection Fraction

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Background: Ventricular arrhythmias (VA) encompasses a wide range of abnormal cardiac rhythms including monomorphic and polymorphic ventricular tachycardia, ventricular fibrillation, and premature ventricular contractions. Patients with heart failure with reduced ejection fraction (HFrEF) have increased risk of ventricular arrhythmias, ultimately leading to increased mortality. Baroreflex Activation Therapy (BAT) employs an implantable device to increase parasympathetic nervous system activity by stimulating the carotid baroreceptors thereby reducing afterload and heart failure symptoms. In this study, we analyzed the effects of BAT on ventricular arrhythmia rates in patients with HFrEF.

Methods: Patients with HFrEF with BAT therapy for at least 12-months at Keck Hospital of USC were retrospectively studied. Inclusion criteria includes implantable cardioverter-defibrillator (ICD) placement of at least 12-months pre- and post-BAT therapy. Ventricular arrhythmia rates 6 and 12-months pre-BAT therapy and 6 and 12-months post-BAT therapy were compared. Ventricular arrhythmia occurrences were recorded through ICD interrogation every 1-3 months in the clinic. Of the 31 identified patients on BAT therapy, 14 patients fit the inclusion criteria. For the 14 patients in the study, 4 identified as female and 10 identified as male, 7 identified as white, 6 identified as Hispanic, and 1 identified as African-American with a mean age of 60.3 ± 15.6 years. The average left ventricular ejection fraction pre-BAT therapy was $22.4 \pm 10.3\%$.

Results: The mean ventricular arrhythmia rates for 6-month pre-BAT therapy and 6-month post-BAT therapy were $0.73/\text{month}$ and $0.26/\text{month}$ respectively ($p=0.28$), suggesting no statistical differences in ventricular arrhythmia rates at 6-months with BAT therapy. The mean average ventricular arrhythmia rates for 12-month pre-BAT therapy and 12-month post-BAT therapy were $0.39/\text{month}$ and $0.14/\text{month}$ respectively ($p=0.26$), suggesting no statistical differences in ventricular arrhythmia rates at 12-months with BAT therapy.

Conclusion: Although BAT therapy has been shown to decrease hospitalization rates, BAT therapy is not associated with decreased ventricular arrhythmia rates at 6 months and 12 months.

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Between the lines of the original article entitled “Mid-term outcomes of surgical aortic valve replacement using a mosaic porcine bioprosthesis with concomitant mitral valve repair”

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Background: Aortic valve disease with concomitant mitral regurgitation (MR) is clinically relevant, particularly in terms of transcatheter interventions involving the aortic and mitral valves. However, a lack of data regarding multivalvular disease has led to the absence of clear evidence-based recommendations. Whether concomitant MR should be treated at the time of surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR) or as a staged strategy is unclear and remains a challenging issue.

Purpose: The aim of the present subgroup analysis was to investigate overall survival as a primary outcome of SAVR using the Mosaic bioprosthesis with concomitant mitral valve (MV) repair in the Japan Mosaic valve (J-MOVE) study cohort. We subsequently sought to identify appropriate patient characteristics by comparing mortality risk, which was defined as a secondary outcome, via statistical analysis of the follow-up data of the J-MOVE cohort.

Methods: This study retrospectively evaluated the mid-term outcomes of SAVR using a stented porcine aortic valve bioprosthesis (Mosaic; Medtronic Inc., Minneapolis, MN, USA) with concomitant MV repair. From 1999 to 2014, 157 patients (median [interquartile range] age, 75 [70–79] years; 47% women) underwent SAVR with concomitant MV repair (SAVR + MV repair), and 1045 patients (median [interquartile range] age, 76 [70–80] years; 54% women) underwent SAVR only at 10 centers in Japan as part of the long-term multicenter J-MOVE study.

Results: The 5-year overall survival rate was $81.5\% \pm 4.1\%$ in the SAVR + MV repair group and $85.1\% \pm 1.4\%$ in the SAVR only group, and the 8-year overall survival rates were $75.2\% \pm 5.7\%$ and $78.1\% \pm 2.1\%$, respectively. Cox proportional hazards analysis showed no significant difference in the survival rates between the two groups (hazard ratio, 0.87; 95% confidence interval, 0.54–1.40; $P = 0.576$). Among women with mild or moderate mitral regurgitation who were not receiving dialysis, those who underwent SAVR + MV repair, were aged > 75 years, and had a preoperative left ventricular ejection fraction of 30–75% tended to have a lower mortality risk.

Conclusion: This subgroup analysis of the J-MOVE cohort showed relevant mid-term outcomes after SAVR + MV repair.

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Progress towards Simulation of Thrombosis in a Temporary LVAD Catheter Pump within Diseased Pulsatile Native Left Hearts

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Background: Percutaneous catheter pumps are intraventricular temporary mechanical circulatory support (MCS) devices that are positioned across the aortic valve into the left ventricle (LV) and provide continuous antegrade blood flow from the LV into the ascending aorta (AA). MCS devices are most often computationally evaluated as isolated devices subject to idealized steady-state blood flow conditions. In clinical practice, MCS devices operate connected to or within diseased pulsatile native hearts and are often complicated by hemocompatibility related adverse events such as stroke, bleeding, and thrombosis. Whereas aspects of the human circulation are increasingly being simulated via computational methods, the precise interplay of pulsatile LV hemodynamics with MCS pump hemocompatibility remains mostly unknown and not well characterized. Technologies are rapidly converging such that next-generation MCS devices will soon be evaluated in virtual physiological environments that increasingly mimic clinical settings. The purpose of this study is to report progress and results from CFD simulations of hemodynamics and thrombosis in a catheter pump situated within virtual diseased pulsatile native left heart environments.

Methods: Various disease states of the heart (e.g., cardiogenic shock, valvular disorders, hypertrophic cardiomyopathy, HFrEF, HFpEF) significantly impact the cardiac pressure-volume loop, and consequently, impact the wall motions of the left heart as well as unsteady pressure distributions in the circulation. Prescribed pulsatile wall motions of the left heart are derived from a lumped parameter model of the human cardiovascular circulation. We have developed a preliminary CFD model to predict detailed left heart hemodynamics under various cardiac disease states. We have integrated this CFD model into bloodDamageFoam, an OpenFOAM-based CFD code, to predict the hemodynamic flow and blood damage for biomedical devices. We will apply bloodDamageFoam to a generic catheter pump inspired by the Impella 5.0 situated within a diseased pulsatile native left heart that includes the left atrium, LV, and AA. The thrombosis model will account for the effects of high shear stress induced activation of von Willebrand factor.

Results: Preliminary results indicate that the CFD-predicted LV pressure waveforms replicate the main features of physiologically expected waveforms. We anticipate that CFD will predict 5.0 LPM of blood flow rate be continuously drawn from the LV and, consequently, modify the pressure-volume loop into a triangular shape. We anticipate that thrombosis predictions will show platelet depositions on the cage of the inlet cannula and within the catheter pump chamber, both of which are being subjected to highly unsteady and non-uniform hemodynamics. We will investigate and compare the thrombotic behaviors in the catheter pump for cardiogenic shock and hypertrophic cardiomyopathy disease states.

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